

PART III: CONSUMER INFORMATION**PrGenotropin GoQuick**

Somatropin [rDNA origin] for injection

This leaflet is part III of a three-part "Product Monograph" published when Genotropin was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Genotropin. Contact your doctor if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

In children, Genotropin is used to treat the following growth problems:

- If you are not growing properly and you do not have enough of your own growth hormone.
- If you have Turner syndrome. Turner syndrome is a chromosomal error in girls that can affect growth - your doctor will have told you if you have this.
- If you have Prader-Willi syndrome, a genetic disorder that can reduce your growth, increase the amount of fat and decrease the amount of muscle in your body - your doctor will have told you if you have this.
- If you were small or too light at birth. Growth hormone **may** help you grow taller if you have not been able to catch up or maintain normal growth by two years of age or later.
- If you have idiopathic (unknown cause) short stature.

In adults, Genotropin is used to treat persons with pronounced growth hormone deficiency. This can start during adult life, or it can continue from childhood.

If you have been treated with Genotropin for growth hormone deficiency during childhood, your growth hormone status will be retested after completion of growth. If severe growth hormone deficiency is confirmed, your doctor will propose continuation of Genotropin treatment.

What it does:

Genotropin is a recombinant human growth hormone (also called somatropin). It has the same structure as natural human growth hormone which is needed for bones and muscles to grow. It also helps your fat and muscle tissues to develop in the right amounts. Recombinant means it is made using bacteria instead of being taken out of human or animal tissue.

When it should not be used:

- You are allergic (hypersensitive) to somatropin or any of the other ingredients of Genotropin.

- You have an active tumour. Tumours must be inactive and you must have finished your anti-tumour treatment before you start using Genotropin.
- You are seriously ill (for example, complications following open heart surgery, abdominal surgery, acute respiratory failure, accidental trauma or similar conditions). If you are about to have, or have had, a major operation, or go into hospital for any reason, tell your doctor and remind the other doctors you are seeing that you use growth hormone.
- Genotropin has been prescribed to stimulate growth but you have already stopped growing (the growth plates on your long bones are closed).
- In patients with Prader-Willi syndrome who are very obese or have severe breathing problems. There have been reports of sudden deaths in children with Prader-Willi syndrome who were treated with growth hormone and had one or more of the following risk factors: severe obesity, breathing problems, colds or lung infections.
- In patients with diabetic retinopathy, a complication of diabetes that results from damage to the blood vessels of the light-sensitive tissue at the back of the eye (retina).
- You have uncontrolled diabetes or active psychosis.

What the medicinal ingredient is:

Genotropin is a recombinant human growth hormone (also called somatropin).

What the important nonmedicinal ingredients are:

Each cartridge in the pre-filled pen contains 5mg, 5.3 mg or 12 mg of somatropin. The Genotropin powder contains glycine, sodium dihydrogen phosphate anhydrous, disodium phosphate anhydrous and mannitol.

The diluent (solution for dissolving somatropin) contains water for injection, mannitol and metacresol.

What dosage forms it comes in:

Genotropin is presented in a cartridge with two sections that is contained in a multi-dose, disposable pre-filled pen called GoQuick. One section contains the powder for solution for injection and the other contains the liquid for solution for injection. The powder is white and the liquid is clear.

When mixed together, the powder and the liquid make 1 ml of solution for injection.

Genotropin is available in pack sizes of 1 GoQuick pre-filled pen and 5 GoQuick pre-filled pens. Not all strengths and pack sizes are marketed in Canada.

WARNINGS AND PRECAUTIONS**Serious Warnings and Precautions**

Before taking GENOTROPIN, talk to your doctor or pharmacist if:

- **The child has Prader-Willi Syndrome and breathing**

problems, sleep apnea (not breathing while sleeping), snoring, severe obesity, uncontrolled diabetes, active psychosis or a respiratory infection.

A doctor trained in hormone and growth disorders must examine the patient to decide if it is safe to use GENOTROPIN.

After the GENOTROPIN powder has been dissolved it must be water-clear and free of particles.

BEFORE using Genotropin, the patient or caregiver should tell the doctor:

- If the patient is at risk of developing diabetes, the doctor will need to monitor their blood sugar level during treatment with Genotropin.
- If the patient has diabetes, they should closely monitor their blood sugar level during treatment with Genotropin and discuss the results with their doctor to determine whether they need to change the dose of their medicines to treat diabetes.
- If the patient is receiving treatment with thyroid hormones it may be necessary to adjust their thyroid hormone dose.
- If the patient is taking growth hormone to stimulate growth and walk with a limp or if they start to limp during their growth hormone treatment due to pain in their hip, they should inform their doctor.
- If the patient develops a strong headache, visual disturbances or vomiting they should inform their doctor about it.
- If their doctor confirms that the patient has developed inflammation of the muscles near the injection site because of the preservative metacresol, they should use a Genotropin product without metacresol.
- If the patient is receiving Genotropin for growth hormone deficiency following a previous tumour, they should be examined regularly for recurrence of the tumour.
- If the patient is a survivor of childhood cancer.
- If the patient, especially a child, develops severe abdominal pain (inflammation of the pancreas).
- If the patient is, or plans to become pregnant or is breast-feeding.
- If the patient develop a limp while being treated with GENOTROPIN.
- If the patient has Turner syndrome and develops an ear infection or headaches her doctor should be told about these problems.
- If the patient has hypopituitarism and is receiving standard hormone replacement therapy, the doctor should monitor the hormone replacement therapy closely during GENOTROPIN treatment.

After starting Genotropin treatment some patients may need to start thyroid hormone replacement.

Progression of pre-existing scoliosis (curvature of the spine) can occur in children who have rapid growth.

The patient should not use Genotropin if they are pregnant or are trying to become pregnant.

INTERACTIONS WITH THIS MEDICATION

Please tell your doctor or pharmacist if you are using or have recently used any other medicines, including medicines obtained without a prescription.

You should tell your doctor if you are using:

- medicines to treat diabetes,
- thyroid hormones,
- synthetic adrenal hormones (corticosteroids),
- sex hormones (for example oral estrogens),
- cyclosporine (a medicine that weakens the immune system after transplantation),
- medicines to control epilepsy (anticonvulsants).

Your doctor may need to adjust the dose of these medicines or the dose of Genotropin.

PROPER USE OF THIS MEDICATION

Recommended dosage

The dose depends on your size, the condition for which you are being treated and how well growth hormone works for you. Everyone is different. Your doctor will advise you about your individualized dose of Genotropin in milligrams (mg) from either your body weight in kilograms (kg), as well as your treatment schedule. Do not change the dosage and treatment schedule without consulting your doctor.

Children with growth hormone deficiency:

0.16-0.24 mg/kg body weight per week. Higher doses can be used. When growth hormone deficiency continues into adolescence, Genotropin should be continued until completion of physical development.

Children with Turner syndrome:

0.33 mg/kg body weight per week.

Children with idiopathic short stature:

UP TO 0.47 mg/kg body weight per week

Children born smaller or lighter than expected and with growth disturbance:

UP TO 0.48 mg/kg body weight per week. Your doctor will determine the most appropriate dose and length of treatment. Treatment should be discontinued if: i) after the first year if you are not responding or ii) if you have reached your final height and stopped growing.

Adults with growth hormone deficiency:

You should start with 0.15-0.3 mg per day.

This dosage should be gradually increased or decreased according to blood test results as well as clinical response and side effects.

Children with Prader-Willi syndrome:

0.035 mg/kg body weight per day or 1.0 mg/m² body surface area per day. The weekly dosage should not exceed 0.24 mg/kg. Treatment should not be used in children who have almost stopped growing after puberty.

If you are a woman on oral estrogen replacement, a higher dose of growth hormone may be required to achieve the treatment goal. Conversely, if you are a woman on somatropin and you discontinue oral estrogen therapy, the dose of somatropin may need to be reduced to avoid excess of growth hormone and/or side effects.

Follow the instructions given to you by your doctor.

Injecting Genotropin

Genotropin is intended for subcutaneous use. This means that it is injected through a short injection needle into the fatty tissue just under your skin. Your doctor should have already shown you how to use Genotropin. Always inject Genotropin exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Read carefully the GoQuick Instructions for Use included in this package leaflet. You must use the pen as described in the Instructions for Use.

The needle must be screwed on to the GoQuick pen before mixing. Use a new needle before each injection. Needles must not be re-used.

- **Preparing the injection:**

You can take your Genotropin out of the refrigerator up to 2 hours before your injection. This lets it warm up slightly and can make your injections more comfortable. Once the injection is administered, the reconstituted solution must be returned to the refrigerator. The cycle can be repeated over the allowable 4 week period.

The two-chamber cartridge that contains both the growth hormone and the dissolving liquid is contained in the GoQuick pen. The growth hormone and the dissolving liquid are mixed together by twisting the cartridge holder (see the detailed steps in Instructions for Use). Dissolve the powder by gently tipping the GoQuick pen back and forth 5-10 times until the powder is dissolved.

When you are mixing your Genotropin, **DO NOT SHAKE** the pen. Mix it gently. Shaking the solution could make your growth hormone foam and damage the active substance. Check the solution and do not inject if the solution is cloudy or has particles in it.

- **Injecting Genotropin:**

Remember to wash your hands and clean your skin first.

Inject your growth hormone at about the same time every day. Bedtime is a good time because it is easy to remember. It is also natural to have a higher level of growth hormone at night.

Most people do their injections into their thigh or their bottom. Do your injection in the place you have been shown by your doctor. Fatty tissue of the skin can shrink at the site of injection. To avoid this, use a slightly different place for your injection each time. This gives your skin and the area under your skin time to recover from one injection before it gets another one in the same place.

Remember to put your Genotropin back in the refrigerator straight after your injection.

If you use more Genotropin than you should

If you inject much more than you should, contact your doctor or pharmacist as soon as possible. Your blood sugar level could fall too low and later rise too high. You might feel shaky, sweaty, sleepy or “not yourself”, and you might faint.

If you forget to use Genotropin

Do not use a double dose to make up for a forgotten dose. It is best to use your growth hormone regularly. If you forget to use a dose, have your next injection at the usual time the next day. Keep a note of any missed injections and tell your doctor at your next check-up.

If you stop using Genotropin

Ask for advice from your doctor before you stop using Genotropin.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, Genotropin can cause side effects, although not everybody gets them.

Common side effects (likely to occur in fewer than 1 in 10 patients) include:

Formation of antibodies to the injected growth hormone but these do not seem to stop the growth hormone from working.

In children:

- Temporary reddening, itchiness or pain at the injection site.
- Rash
- Raised itchy bumps on the skin

In adults:

- Numbness / tingling,
- Stiffness in the arms and legs, joint pain, muscle pain,
- Water retention (which shows as puffy fingers or swollen ankles). These symptoms may be seen for a short time at the start of treatment, but they

disappear spontaneously or when the dosage is lowered.

These common side effects in adults may start within the first months of treatment and may either stop spontaneously or if your dose is reduced.

Uncommon side effects (likely to occur in fewer than 1 in 100 patients) include:

In children:

- Numbness / tingling,
- Stiffness in the arms and legs, joint pain, muscle pain,
- Water retention (which shows as puffy fingers or swollen ankles, for a short time at the start of treatment).
- Itching

In adults:

- Pain or burning sensation in the hands or underarms (known as Carpal Tunnel Syndrome).

Rare side effects (likely to occur in fewer than 1 in 1,000 patients) include:

- Type 2 diabetes mellitus,
- Intracranial hypertension (increased pressure within the skull due to swelling of the brain) which causes symptoms such as a strong headache that doesn't go away, vision problems, nausea or vomiting. Call your doctor if the patient has any of these symptoms.
- Rash
- Itching
- Raised itchy bumps on the skin

Very rare side effects (likely to occur in fewer than 1 in 10,000 patients) include:

- Leukemia
- hair loss
- aggressiveness
- headache
- back pain

The skin around the injection area can get uneven or lumpy, but this should not happen if you inject in a different place each time.

A very rare side effect that can occur because of the preservative metacresol is inflammation of the muscles near the injection site. If your doctor confirms that you have developed this, you should use a Genotropin product without metacresol.

Slipped capital femoral epiphysis and Legg-Calve-Perthes disease may be considered by your doctor if discomfort or pain in the hip or knee is experienced whilst being treated with Genotropin.

Since Genotropin has been on the market, serious strong reactions have occurred in patients including very bad allergic reactions that can cause difficulty breathing and swelling of

the face and lips. Patients and caregivers should get medical attention immediately if an allergic reaction occurs.

There have been rare cases of sudden death in patients with Prader-Willi syndrome. However, no link has been made between these cases and treatment with Genotropin.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

This is not a complete list of side effects. For any unexpected effects while taking Genotropin, contact your doctor or treatment center.

HOW TO STORE IT

Keep out of the reach and sight of children.

Do not use Genotropin after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.

Before mixing the powder with the liquid, your growth hormone should be stored in a refrigerator (2° to 8°C) until no later than the expiry date. It can be stored for a maximum of 4 weeks unrefrigerated (at or below 25°C). During and/or at the end of the 4 weeks period, the product should not be put back in the refrigerator. After this it must be discarded.

Genotropin is sensitive to light. You should keep the GoQuick pen in the outer carton in order to protect your Genotropin from light.

After mixing the powder with the liquid, Genotropin must be stored in a refrigerator (2° to 8°C), for up to 4 weeks. The reconstituted solution can remain at room temperature for up to 2 hours prior to each injection. Once the injection is administered, the reconstituted solution must be returned to the refrigerator. The cycle can be repeated over the allowable 4 week period. If you use the needle guard, store your pen with the needle guard and black cap in place. If you do not use the needle guard, store your pen with the white pen cap in place. See the Instructions for Use. These measures will help to protect your Genotropin from light.

Do not freeze or expose Genotropin to frost. If it freezes, do not use it.

Never throw away needles with your ordinary garbage. When you have finished with a needle, you must discard it carefully so that no-one will be able to use it or prick themselves on it. You can get a special "sharps" bin from your hospital or growth clinic.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to:
Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at www.pfizer.ca or can be obtained by contacting the sponsor, Pfizer Canada ULC, at: 1-800-463-6001 (Medical Information)

This leaflet was prepared by Pfizer Canada ULC
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PART III: CONSUMER INFORMATION**PrGenotropin MiniQuick**

Somatotropin [rDNA origin] for injection

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ABOUT THIS MEDICATION**What the medication is used for:**

In children, Genotropin MiniQuick is used to treat growth problems:

- If you are not growing properly and you do not have enough of your own growth hormone.
- If you have Turner syndrome. Turner syndrome is a chromosomal error in girls that can affect growth - your doctor will have told you if you have this.
- If you have Prader-Willi syndrome, a genetic disorder that can reduce your growth, increase the amount of fat and decrease the amount of muscle in your body - your doctor will have told you if you have this.
- If you were small or too light at birth. Growth hormone **may** help you grow taller if you have not been able to catch up or maintain normal growth by two years of age or later.
- If you have idiopathic (unknown cause) short stature.

In adults, Genotropin MiniQuick is used to treat persons with pronounced growth hormone deficiency. This can start during adult life, or it can continue from childhood.

If you have been treated with Genotropin MiniQuick for growth hormone deficiency during childhood, your growth hormone status will be retested after completion of growth. If severe growth hormone deficiency is confirmed, your doctor will propose continuation of Genotropin MiniQuick treatment.

What it does:

Genotropin MiniQuick is a recombinant human growth hormone (also called somatotropin). It has the same structure as natural human growth hormone which is needed for bones and muscles to grow. It also helps your fat and muscle tissues to develop in the right amounts. Recombinant means it is made using bacteria instead of being taken out of human or animal tissue.

When it should not be used:

- You are allergic (hypersensitive) to somatotropin or any of the other ingredients of Genotropin MiniQuick.
- You have an active tumour. Tumours must be inactive and you must have finished your anti-tumour treatment before you start using Genotropin MiniQuick.

- You are seriously ill (for example, complications following open heart surgery, abdominal surgery, acute respiratory failure, accidental trauma or similar conditions). If you are about to have, or have had, a major operation, or go into hospital for any reason, tell your doctor and remind the other doctors you are seeing that you use growth hormone.
- Genotropin MiniQuick has been prescribed to stimulate growth but you have already stopped growing (the growth plates on your long bones are closed).
- In patients with Prader-Willi syndrome who are very obese or have severe breathing problems. There have been reports of sudden deaths in children with Prader-Willi syndrome who were treated with growth hormone and had one or more of the following risk factors: severe obesity, breathing problems, colds or lung infections.
- In patients with diabetic retinopathy, a complication of diabetes that results from damage to the blood vessels of the light-sensitive tissue at the back of the eye (retina).
- You have uncontrolled diabetes or active psychosis.

What the medicinal ingredient is:

The active substance is recombinant somatotropin.

What the important nonmedicinal ingredients are:

Each syringe contains 0.2 mg, 0.4 mg, 0.6 mg, 0.8 mg, 1.0 mg, 1.2 mg, 1.4 mg, 1.6 mg, 1.8 mg, or 2.0 mg of somatotropin. The other ingredients in the powder are: glycine, mannitol, sodium dihydrogen phosphate anhydrous, and disodium phosphate anhydrous. The ingredients in the liquid are: water for injection and mannitol.

Genotropin MiniQuick does not contain preservatives.

What dosage forms it comes in:

Genotropin MiniQuick is presented in a cartridge with two sections, in a single dose syringe. One section contains the powder for solution for injection and the other contains the liquid for solution for injection. The powder is white and the liquid is clear.

When mixed together, the powder and the liquid make 0.25 ml of solution for injection.

Genotropin MiniQuick is available in pack sizes of 4 syringes, 7 syringes and 28 syringes. Not all strengths and pack sizes are marketed in Canada.

WARNINGS AND PRECAUTIONS**Serious Warnings and Precautions**

Before taking GENOTROPIN, talk to your doctor or pharmacist if:

- **The child has Prader-Willi Syndrome and breathing problems, sleep apnea (not breathing while sleeping), snoring, severe obesity, uncontrolled diabetes, active psychosis or a respiratory infection.**

A doctor trained in hormone and growth disorders must examine the patient to decide if it is safe to use GENOTROPIN.

After the GENOTROPIN powder has been dissolved it must be water-clear and free of particles.

BEFORE using Genotropin, the patient or caregiver should tell the doctor:

- If the patient is at risk of developing diabetes, the doctor will need to monitor their blood sugar level during treatment with Genotropin.
- If the patient has diabetes, they should closely monitor their blood sugar level during treatment with Genotropin and discuss the results with their doctor to determine whether they need to change the dose of their medicines to treat diabetes.
- If the patient is receiving treatment with thyroid hormones it may be necessary to adjust their thyroid hormone dose.
- If the patient is taking growth hormone to stimulate growth and walk with a limp or if they start to limp during their growth hormone treatment due to pain in their hip, they should inform their doctor.
- If the patient develops a strong headache, visual disturbances or vomiting they should inform their doctor about it.
- If their doctor confirms that the patient has developed inflammation of the muscles near the injection site because of the preservative metacresol, they should use a Genotropin product without metacresol.
- If the patient is receiving Genotropin for growth hormone deficiency following a previous tumour, they should be examined regularly for recurrence of the tumour.
- If the patient is a survivor of childhood cancer.
- If the patient, especially a child, develops severe abdominal pain (inflammation of the pancreas).
- If the patient is, or plans to become pregnant or is breast-feeding.
- If the patient develop a limp while being treated with GENOTROPIN.
- If the patient has Turner syndrome and develops an ear infection or headaches her doctor should be told about these problems.
- If the patient has hypopituitarism and is receiving standard hormone replacement therapy, the doctor should monitor the hormone replacement therapy closely during GENOTROPIN treatment.

After starting Genotropin treatment some patients may need to start thyroid hormone replacement.

Progression of pre-existing scoliosis (curvature of the spine) can occur in children who have rapid growth.

The patient should not use Genotropin if they are pregnant or are trying to become pregnant.

INTERACTIONS WITH THIS MEDICATION

Please tell your doctor or pharmacist if you are using or have recently used any other medicines, including medicines obtained without a prescription.

You should tell your doctor if you are using:

- medicines to treat diabetes,
- thyroid hormones,
- synthetic adrenal hormones (corticosteroids),
- sex hormones (for example oral estrogens),
- cyclosporine (a medicine that weakens the immune system after transplantation),
- medicines to control epilepsy (anticonvulsants).

Your doctor may need to adjust the dose of these medicines or the dose of Genotropin MiniQuick.

PROPER USE OF THIS MEDICATION

Recommended dosage

The dose depends on your size, the condition for which you are being treated and how well growth hormone works for you. Everyone is different. Your doctor will advise you about your individualized dose of Genotropin in milligrams (mg) from either your body weight in kilograms (kg), as well as your treatment schedule. Do not change the dosage and treatment schedule without consulting your doctor.

Children with growth hormone deficiency:
0.16-0.24 mg/kg body weight per week. Higher doses can be used. When growth hormone deficiency continues into adolescence, Genotropin should be continued until completion of physical development.

Children with Turner syndrome:
0.33 mg/kg body weight per week.

Children with idiopathic short stature:
UP TO 0.47 mg/kg body weight per week

Children born smaller or lighter than expected and with growth disturbance:
UP TO 0.48 mg/kg body weight per week. Your doctor will determine the most appropriate dose and length of treatment. Treatment should be discontinued if: i) after the first year if you are not responding or ii) if you have reached your final height and stopped growing.

Adults with growth hormone deficiency:
Adults with growth hormone deficiency:
You should start with 0.15-0.3 mg per day.
This dosage should be gradually increased or decreased according to blood test results as well as clinical response and side effects.

Children with Prader-Willi syndrome:
0.035 mg/kg body weight per day or 1.0 mg/m² body surface area per day. Treatment should not be used in children who have almost stopped growing after puberty.

If you are a woman on oral estrogen replacement, a higher dose of growth hormone may be required to achieve the treatment goal. Conversely, if you are a woman on somatropin and you discontinue oral estrogen therapy, the dose of somatropin may need to be reduced to avoid excess of growth hormone and/or side effects.

Follow the instructions given to you by your doctor.

Injecting Genotropin MiniQuick

Genotropin MiniQuick is intended for subcutaneous use. This means that it is injected through a short injection needle into the fatty tissue just under your skin. Your doctor should have already shown you how to use Genotropin MiniQuick. Always inject Genotropin MiniQuick exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

If you cannot remember what to do, do not try to do your injection. Ask your doctor to show you again.

You can take your growth hormone out of the refrigerator half an hour before your injection. This lets it warm up slightly and can make your injections more comfortable.

Remember to wash your hands and clean your skin first.

Inject your growth hormone at about the same time every day. Bedtime is a good time because it is easy to remember. It is also natural to have a higher level of growth hormone at night.

Most people do their injections into their thigh or their bottom. Do your injection in the place you have been shown by your doctor. Fatty tissue of the skin can shrink at the site of injection. To avoid it, use a slightly different place for your injection each time. This gives your skin and the area under your skin time to recover from one injection before it gets another one in the same place.

If you use more Genotropin MiniQuick than you should

If you inject much more than you should, contact your doctor or pharmacist as soon as possible. Your blood sugar level could fall too low and later rise too high. You might feel shaky, sweaty, sleepy or “not yourself”, and you might faint.

If you forget to use Genotropin MiniQuick

Do not take a double dose to make up for a forgotten dose. It is best to take your growth hormone regularly. If you forget to take a dose, have your next injection at the usual time the next day. Keep a note of any missed injections and tell your doctor at your next check-up.

If you stop using Genotropin MiniQuick

Ask for advice from your doctor before you stop using Genotropin MiniQuick.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

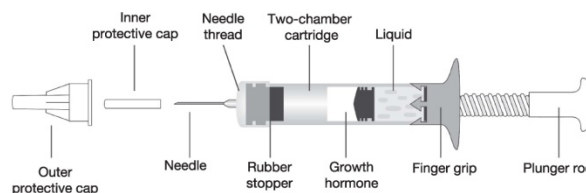
Detailed Instructions for use

Genotropin MiniQuick is a syringe used to mix and administer a single dose of Genotropin (growth hormone).

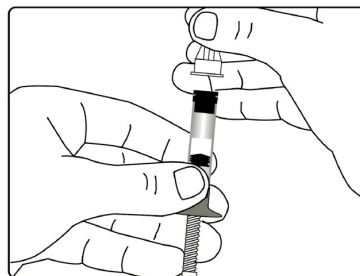
Each Genotropin MiniQuick comes preloaded with a cartridge with two sections and a needle. If you need additional needles, ask for the same Becton Dickinson Micro-Fine needles provided with the MiniQuick. The injection volume is always 0.25 ml.

The Genotropin MiniQuick is disposable; after you have administered a dose, dispose of it as described by your pharmacist.

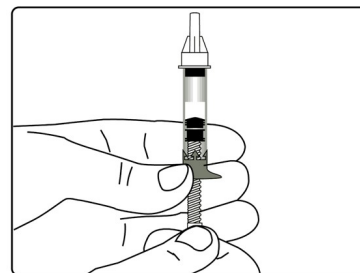
The diagram below identifies the different components.



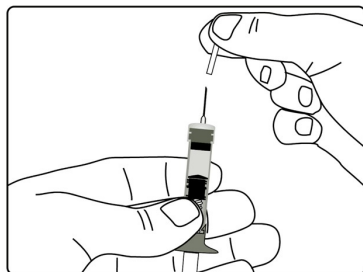
The cartridge of Genotropin MiniQuick contains the growth hormone powder in one section and a liquid in the other. When you turn the plunger rod clockwise, the growth hormone powder and the liquid mix and the powder dissolves.



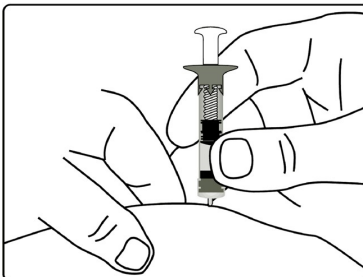
1. Peel the paper covering from the injection needle. Attach the needle onto the Genotropin MiniQuick by pushing it down and turning it until it no longer can turn. Make sure the needle is positioned squarely onto the end of the rubber stopper before screwing it to the Genotropin MiniQuick.



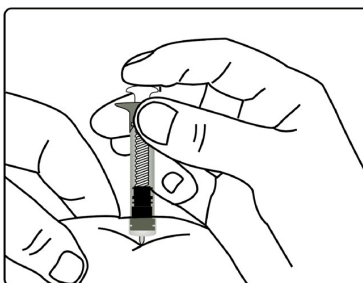
2. Hold the Genotropin MiniQuick with the needle pointing upwards. Turn the plunger rod clockwise until it will go no further. DO NOT shake the solution. Mix it gently. Shaking the solution could make your growth hormone foam and damage the active substance. Check the solution for clarity, and only use clear solutions that are particle free.



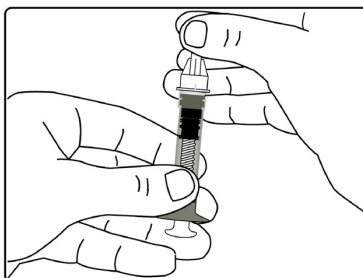
3. Remove the inner and outer protective caps of the needle.



4. Pinch a fold of skin at the injection site firmly and push the needle into the skinfold.



5. Push the plunger rod as far as possible to inject the entire content of the Genotropin MiniQuick. Wait a few seconds before withdrawing the needle to ensure that all the growth hormone is injected.



6. After injection replace the outer protective cap on the needle. Follow your standard guidelines for disposal of syringe and needle.

Additional Information

Is it a problem if I see air bubbles in the syringe?

No. There is no need to remove the air from Genotropin MiniQuick. The small amount of air in the syringe has no consequence on the injection.

What should I do if there is resistance when I turn the plunger rod (step 2) or when I make the injection (step 5)?

The resistance could be because the needle has been inserted at an angle into the rubber stopper. Carefully replace the outer protective cap (the opaque white one) over the needle and unscrew counter clockwise to remove the needle. Hold the MiniQuick syringe with the needle-end pointing up and reposition the needle squarely on top of the syringe. Screw the needle into the syringe.

What should I do if the needle is damaged or bent?

Discard the needle and use a new needle with the MiniQuick.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, Genotropin MiniQuick can cause side effects, although not everybody gets them.

Common side effects (likely to occur in fewer than 1 in 10 patients) include:

Formation of antibodies to the injected growth hormone but these do not seem to stop the growth hormone from working.

In children:

- Temporary reddening, itchiness or pain at the injection site.
- Rash
- Raised itchy bumps on the skin

In adults:

- Numbness / tingling,
- Stiffness in the arms and legs, joint pain, muscle pain,
- Water retention (which shows as puffy fingers or swollen ankles). These symptoms may be seen for a short time at the start of treatment, but they disappear spontaneously or when the dosage is lowered.

These common side effects in adults may start within the first months of treatment and may either stop spontaneously or if your dose is reduced.

Uncommon side effects (likely to occur in fewer than 1 in 100 patients) include:

In children:

- Numbness / tingling,
- Stiffness in the arms and legs, joint pain, muscle pain,
- Water retention (which shows as puffy fingers or swollen ankles, for a short time at the start of treatment).
- Itching

In adults:

- Pain or burning sensation in the hands or underarms (known as Carpal Tunnel Syndrome).

Rare side effects (likely to occur in fewer than 1 in 1,000 patients) include:

- Type 2 diabetes mellitus,
- Intracranial hypertension (increased pressure within the skull due to swelling of the brain) which causes symptoms such as a strong headache that doesn't go away, vision problems, nausea or vomiting. Call your doctor if the patient has any of these symptoms.
- Rash
- Itching
- Raised itchy bumps on the skin

Very rare side effects (likely to occur in fewer than 1 in 10,000 patients) include:

- Leukemia
- hair loss
- aggressiveness
- headache
- back pain

The skin around the injection area can get uneven or lumpy, but this should not happen if you inject in a different place each time.

Slipped capital femoral epiphysis and Legg-Calve-Perthes disease may be considered by your doctor if discomfort or pain in the hip or knee is experienced whilst being treated with Genotropin.

Since Genotropin has been on the market, serious strong reactions have occurred in patients including very bad allergic reactions that can cause difficulty breathing and swelling of the face and lips. Patients and caregivers should get medical attention immediately if an allergic reaction occurs.

There have been rare cases of sudden death in patients with Prader-Willi syndrome. However, no link has been made between these cases and treatment with Genotropin.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

This is not a complete list of side effects. For any unexpected effects while taking Genotropin, contact your doctor or treatment center.

HOW TO STORE IT

Keep out of the reach and sight of children.

Do not use Genotropin MiniQuick after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.

Before mixing the powder with the liquid, your growth hormone should be stored in a refrigerator (2°C to 8°C) until the expiry date. It can be stored for up to 6 months unrefrigerated (at or below 25°C). During and/or at the end of this 6 months period, the product should not be put back in the refrigerator. After this it must be discarded.

Genotropin MiniQuick is sensitive to light. You should keep the container in the outer carton in order to protect your Genotropin MiniQuick from light.

After mixing the powder with the liquid, you should use your growth hormone immediately. If necessary you can store it in the refrigerator (2°C to 8°C) for up to 24 hours in the outer carton in order to protect your Genotropin MiniQuick from light. If you do not use it within 24 hours, do not use it.

Do not freeze or expose Genotropin MiniQuick to frost. If it freezes, do not use it.

Do not use Genotropin MiniQuick if you notice particles, if the solution is not clear or if it has frozen.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

Never throw away needles or empty syringes with your ordinary garbage. When you have finished with a needle, you must discard it carefully so that no-one will be able to use it or prick themselves on it. You can get a special 'sharps' bin from your hospital or growth clinic.

These measures will help to protect the environment.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to:
 - Canada Vigilance Program
 - Health Canada
 - Postal Locator 0701E
 - Ottawa, Ontario
 - K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at www.pfizer.ca or can be obtained by contacting the sponsor, Pfizer Canada ULC, at: 1-800-463-6001 (Medical Information)

This leaflet was prepared by Pfizer Canada ULC
Last revised L3 28 July 2020

GENOTROPIN®GOQUICK™ 5

INSTRUCTIONS FOR USE

Important Information

Please read these instructions completely before using GoQuick.

If you have any questions about your dose or your treatment with Genotropin, call your doctor or nurse.

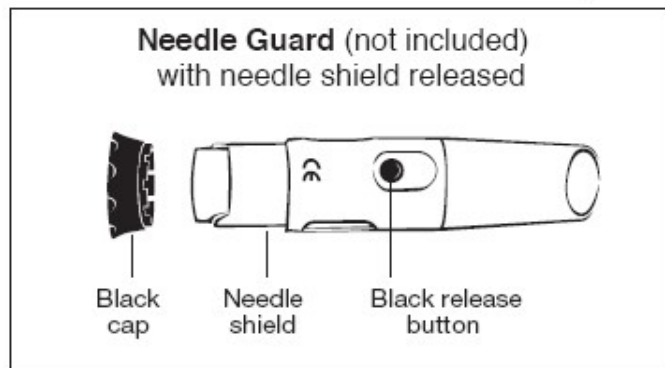
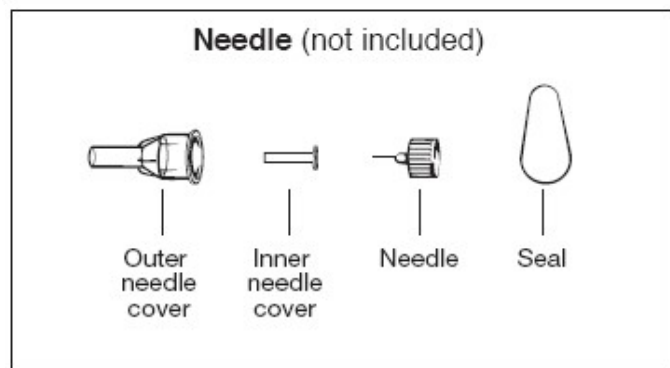
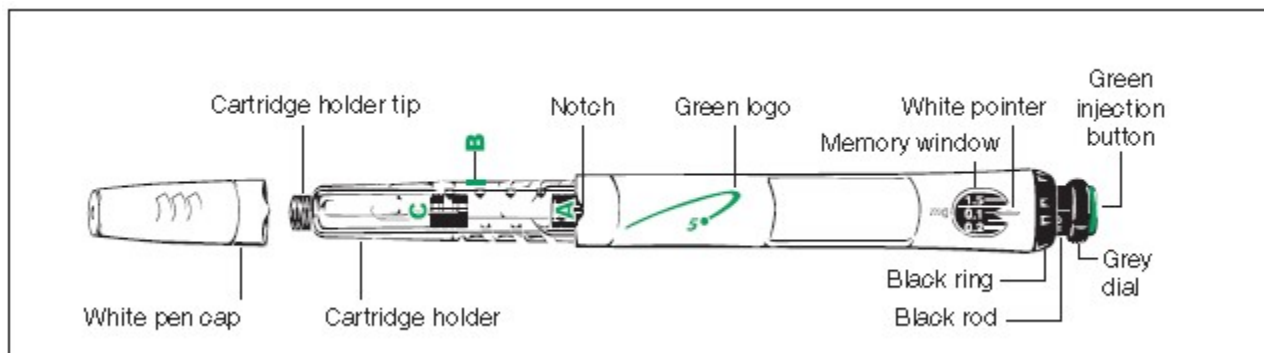
About GoQuick

GoQuick is a prefilled, multidose, disposable injection pen that holds 5.0 mg of somatropin. After reconstitution the concentration of somatropin is 5.0 mg per mL. The Genotropin in the pen is mixed only once, when you start a new pen. A single pen can be used up to 28 days after mixing. You never have to change cartridges. When the pen is empty, you just start a new pen.

The pen has dose memory. The dose is set once on a new pen. The pen then gives the same dose for each injection. You can use the pen with or without the optional needle guard.

Before You Use GoQuick

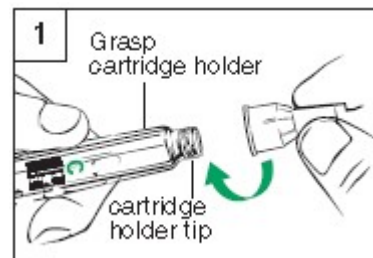
- Get training from your doctor or nurse.
- Know your dose. Know the pen parts.
- Make sure you have the pen with the green injection button.
- Wash your hands.



Setting Up and Using a New GoQuick

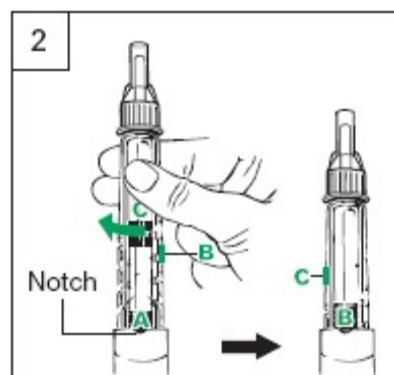
Step 1. Attach the Needle

- Pull the white pen cap straight off the pen.
- Peel the seal from a new needle.
- Firmly grasp the cartridge holder. (Figure 1)
- Push the needle onto the cartridge holder tip.
- Gently screw the needle onto the pen. Do not overtighten.
- Leave both needle covers on the needle.



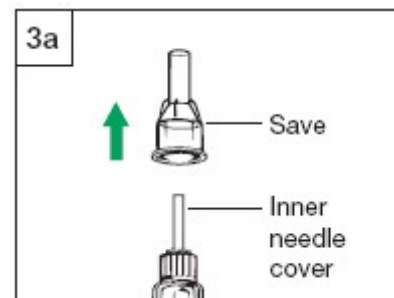
Step 2. Mix the Genotropin

- Hold the pen with the needle-end pointing up and the A facing you. (Figure 2)
- Firmly** twist the cartridge holder into the pen until B clicks into the notch.
 - Gently tilt the pen from side to side. Do not shake the pen. Shaking may damage the growth hormone.
- Check that the liquid in the cartridge is clear. All the powder should be dissolved.
 - If not, gently tilt the pen from side to side a few more times.
- Check the liquid again. Make sure it is clear.
 - If the liquid is clear, go to Step 3.
 - If the liquid is still cloudy or you see any powder, use a new pen.

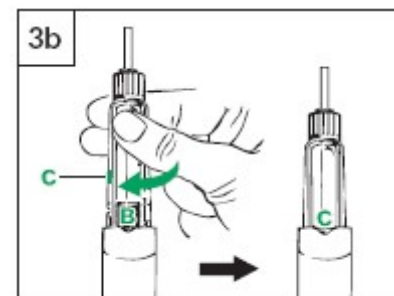


Step 3. Remove the Air

- Pull the outer needle cover off. Save it to re-cap the needle. (Figure 3a)
- Leave the inner needle cover on.

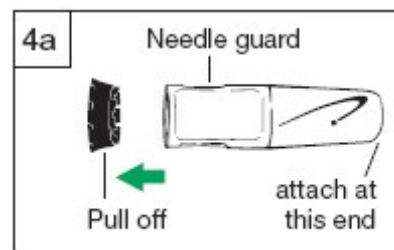


- Hold the pen with the needle-end pointing up. (Figure 3b)
- Tap the cartridge holder gently to help any trapped air move to the top.
- Firmly**, twist the cartridge holder into the pen until C clicks into the notch.
 - Some liquid may appear around the inner needle cover.

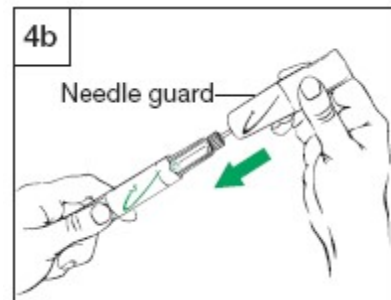


Step 4. Attach the Needle Guard (Optional)

- Pull the black cap off the needle guard. (Figure 4a)
 - If the needle shield slides out, push it back into the needle guard until it clicks into place.

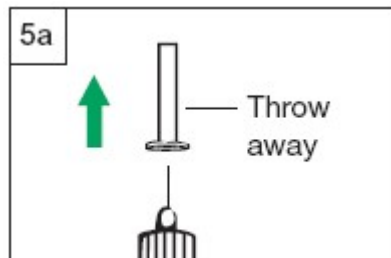


- Hold the pen in one hand below the green logo. With the other hand, hold the needle guard below the needle shield. (Figure 4b)
- Line up the black logo on the needle guard with the green logo on the pen. Carefully push the needle guard onto the pen until it snaps into place.

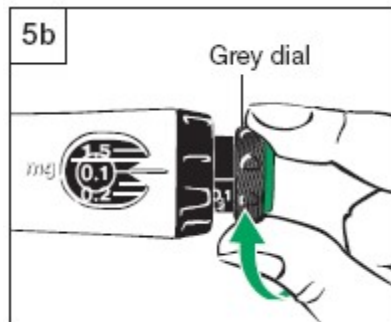


Step 5. Prime the Pen

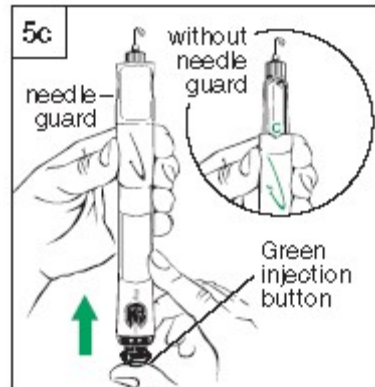
- Pull the inner needle cover off. Throw it away. (Figure 5a)



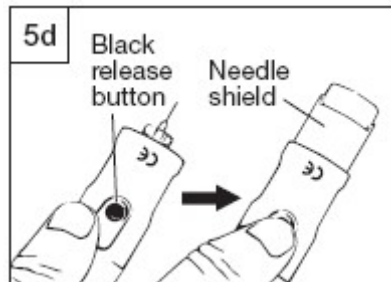
- Check that 0.1 mg is set in the memory window.
- Turn the grey dial in the direction of the arrows until it stops clicking. (Figure 5b)



- Hold the pen with the needle pointing up. (Figure 5c with and without needle guard)
- Push the green injection button until liquid appears.
- If liquid does not appear at Step “e”, repeat Steps b-e in this section up to two more times.
- If liquid still does not appear, do not use the pen.
 - See the Questions and Answers section below for more information.



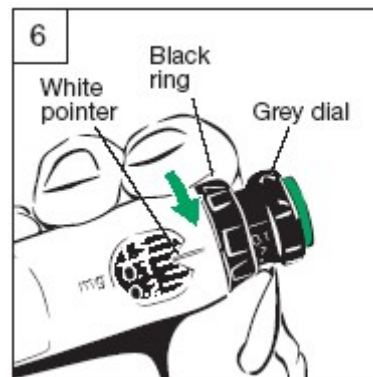
- If you use the needle guard, press the black button to release the needle shield. (Figure 5d)



Step 6. Set the Dose

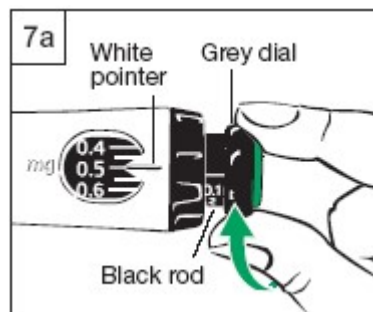
- Use the black ring to set the dose. Be careful not to turn the grey dial while setting the dose.
- a. Hold the black ring as shown in Figure 6.
 - b. Turn the black ring until your dose lines up with the white pointer. Your doctor or nurse has told you your dose.
 - c. If you turn your dose past the white pointer, just turn the black ring back to set the correct dose.
 - d. Once you have set your dose, do not change it unless your doctor or nurse tells you.

Note: If you cannot turn the black ring, press in the green injection button until it stops clicking. Then continue to set your dose using the black ring (for more information, see also the Questions and Answers section below).

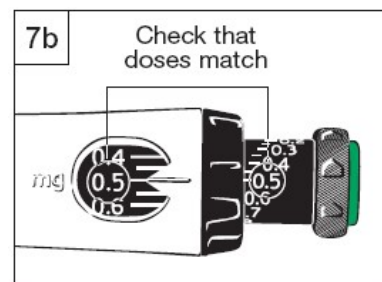


Step 7. Draw Up a Dose

- a. Turn the grey dial in the direction of the arrow until the clicking stops. (Figure 7a)
- b. Your dose on the black rod should line up with the white pointer.

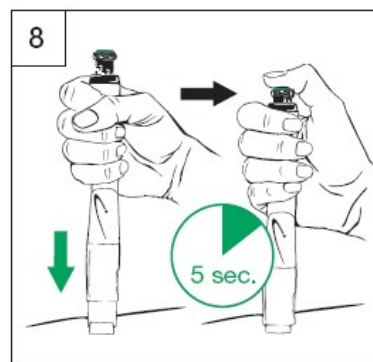


- c. Check that the dose you drew up on the black rod is the same as the dose you set in the memory window. Figure 7b shows an example.
- d. If the doses do not match, make sure you have turned the grey dial in the direction of the arrow until it does not click anymore.



Step 8. Give the Injection

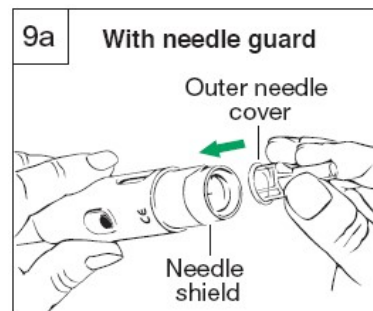
- a. Prepare an injection site as your doctor or nurse has told you.
- b. Hold the pen over the injection site.
- c. Push the pen down to insert the needle into the skin.
- d. Using your thumb, push the green injection button down until it stops clicking. (Figure 8)
 - Count for 5 seconds before you pull the needle out of the skin. Keep light pressure on the button with your thumb while you count.
- e. Pull the pen straight out from the skin.



Step 9. Remove the Needle; Cap and Store Your Pen

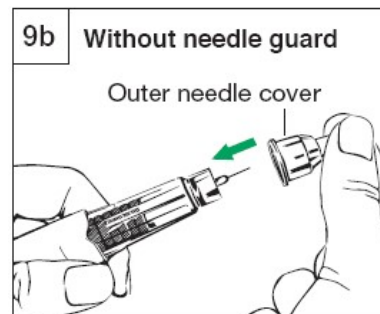
Step 9a: With needle guard

- a. Place the outer needle cover into the end of the needle shield. (Figure 9a)
- b. Use the needle cover to push in the needle shield until it locks into place.
- c. Use the needle cover to unscrew the needle and put it in a proper container for used needles.
- d. Leave the needle guard on the pen.
- e. Place the black cap on the needle guard. Store your pen in the refrigerator.



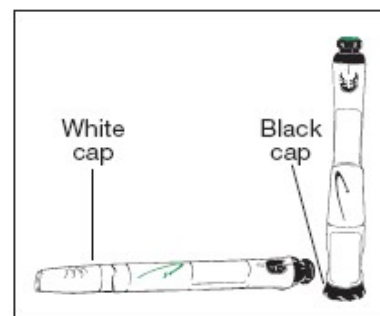
Step 9b: Without needle guard

- a. Do not touch the needle.
- b. Carefully cap the needle with the outer needle cover. (Figure 9b)
- c. Use the needle cover to unscrew the needle and put it in a proper container for used needles.
- d. Place the white cap on the pen. Store your pen in the refrigerator.



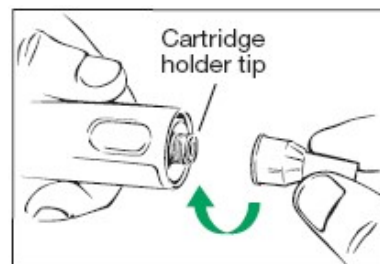
Routine Use of GoQuick

1. Pull the black cap from the needle guard or the white cap from the pen.

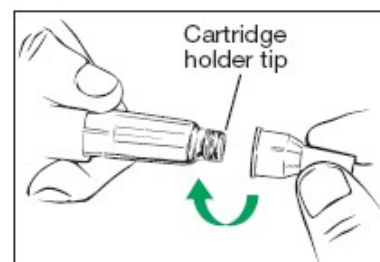


2. Attach a new needle.

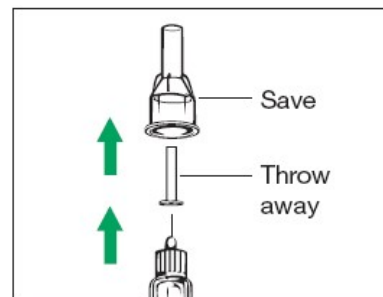
- With the needle guard:
 - If the needle shield releases, push it back into place.
 - Attach a new needle to the cartridge holder tip.



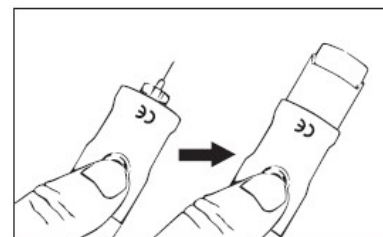
- Without the needle guard:
 - Attach a new needle to the cartridge holder tip.



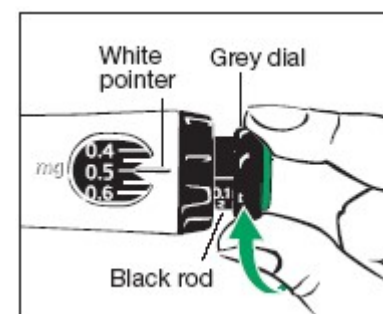
3. Remove both needle covers. Save the outer needle cover.



4. If you use the needle guard, press the black release button to extend the needle shield.

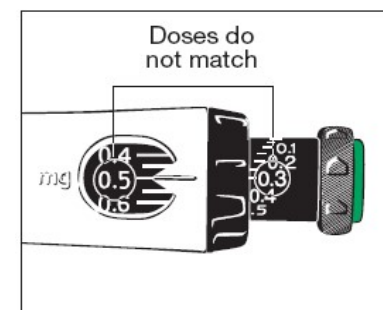


5. To draw up the dose, turn the grey dial until it stops clicking.



6. Check that the dose you drew up is the same as the dose you set in the memory window.

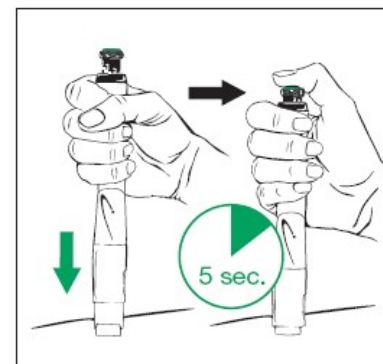
- If the dose you drew up is smaller, the pen does not have a full dose of Genotropin.
- Follow what your doctor or nurse told you to do when the pen does not have a full dose left.



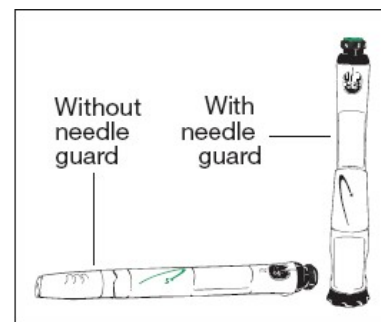
7. Prepare an injection site as your doctor or nurse has told you.

8. Give the injection.

- Push the pen down to insert the needle into the skin.
- Push the green injection button down until it stops clicking.
- Count for 5 seconds before you pull the needle out of the skin. Keep light pressure on the button with your thumb while you count.
- Pull the pen straight out from the skin.



9. Remove the needle.
- With the needle guard:
 - Use the outer needle cover to push in the needle shield until it locks into place.
 - Without the needle guard:
 - Carefully cap the needle with the outer needle cover.
 - Use the outer needle cover to unscrew the needle. Throw the needle away in a proper container for used needles.
10. Cap your needle guard or pen and store it in the refrigerator.



ADDITIONAL INFORMATION

Storage

- See the other side of this leaflet for how to store your GoQuick.
- After 4 weeks, dispose of the pen (or discard) even if there is some medicine left.
- Do not freeze or expose GoQuick to frost.
- Do not use your GoQuick after its expiry date.
- Follow your local health and safety laws to dispose of (or discard) your pen. Ask your doctor or nurse, if you are not sure what to do.

Handling

- Do not mix the powder and liquid of GoQuick unless a needle is on the pen.
- Do not store your GoQuick with the needle attached. The Genotropin may leak from the pen and air bubbles may form in the cartridge. Always remove the needle and attach the pen cap or needle guard cap before storing.
- Take care not to drop your GoQuick.
- If you do drop the pen you must perform another prime as described in Step 5 (Setting Up and Using a New GoQuick). But if any part of your GoQuick appears broken or damaged, do not use the pen. Contact your doctor or nurse for another pen.
- Clean the pen and needle guard with a damp cloth. Do not put the pen in water.

Needles

- Always use a new needle for each injection.
- Put all used needles in an appropriate “sharps” container. Follow your local health and safety laws to dispose of your needles. Ask your doctor or nurse, if you are not sure what to do.
- Do not share your pen or needles.

General

- The numbers and lines on the cartridge holder can help you estimate how much Genotropin is left in the pen.
- If in routine use Step 6 the pen does not have a full dose of Genotropin, the scale on the black rod indicates the amount of drug remaining in the pen.
- Patients who are blind or who do not see well should only use GoQuick with the help of someone trained to use the pen.
- Follow your doctor or nurse’s instructions for cleaning your hands and skin when you prepare and give the injection.
- Do not discard your needle guard, to remove it from the pen just twist it off. Save it to use with each new pen.
- If you have questions about how to use GoQuick, ask your doctor or nurse.

QUESTIONS AND ANSWERS

Question

What should I do if I see more than a small drop of liquid on the needle after giving my injection?

Answer

For your next injection wait the full time of 5 seconds before taking the needle from the skin. If you still see some liquid after you take out the needle, hold in for a little longer next time.

Is it a problem if I see air bubbles in the cartridge?

No, small amounts of air may be present in the cartridge during normal use.

What should I do if I see Genotropin leaking from the pen?

Make sure that the needle has been attached correctly.

What should I do if the pen that I am using was not put in the refrigerator overnight?

Discard the pen and use a new GoQuick.

What should I do if I can't turn the black ring?

You have probably accidentally turned the grey dial. If you have turned the grey dial the pen will prevent you from turning the black ring so that your dose does not change during your injection.

To release the black ring, press in the green injection button until it stops. Note that liquid will come out of the needle. Then continue to set your dose using the black ring.

What if my doctor changes my dose when I've already started a pen?

Set the new dose by turning the black ring.

What if I inject the wrong dose?

Call your doctor or nurse immediately and follow his/her instructions.

What if my pen will not prime (i.e. if liquid did not appear in step 5g)?

Call your doctor or nurse and follow his/her instructions.

What doses can my pen deliver?

The pen can deliver doses from 0.10mg to 1.5mg of Genotropin. Each click of the black ring changes the dose by 0.05mg.

GENOTROPIN®GOQUICK™ 5.3

INSTRUCTIONS FOR USE

Important Information

Please read these instructions completely before using GoQuick.

If you have any questions about your dose or your treatment with Genotropin, call your doctor or nurse.

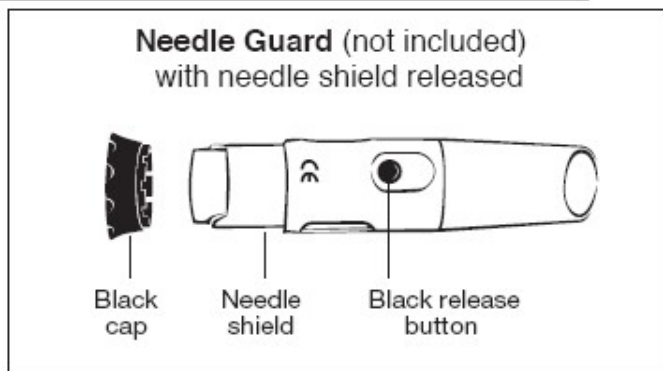
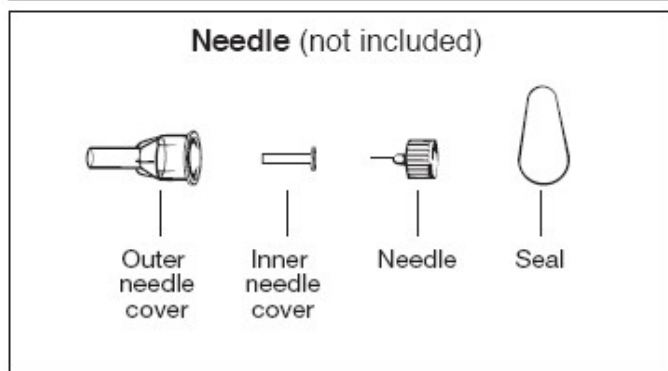
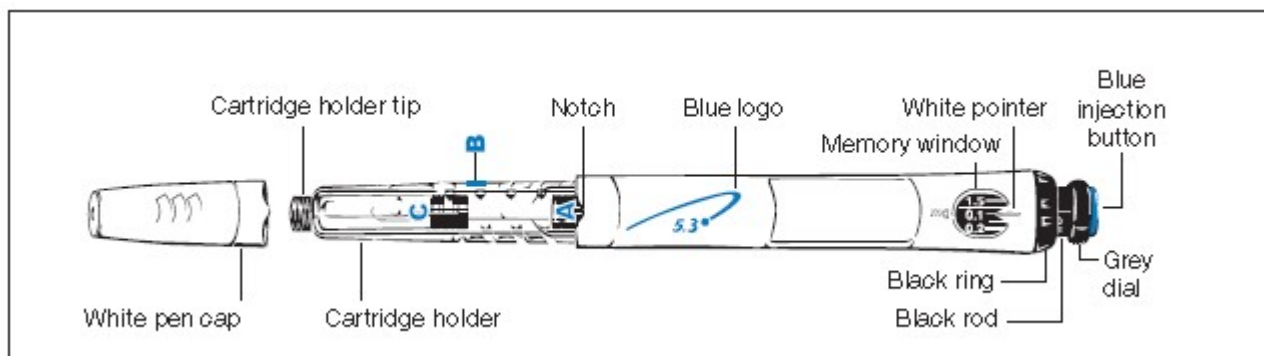
About GoQuick

GoQuick is a prefilled, multidose, disposable injection pen that holds 5.3 mg of somatotropin. After reconstitution the concentration of somatotropin is 5.3 mg per mL. The Genotropin in the pen is mixed only once, when you start a new pen. A single pen can be used for up to 28 days after mixing. You never have to change cartridges. When the pen is empty, you just start a new pen.

The pen has dose memory. The dose is set once on a new pen. The pen then gives the same dose for each injection. You can use the pen with or without the optional needle guard.

Before You Use GoQuick

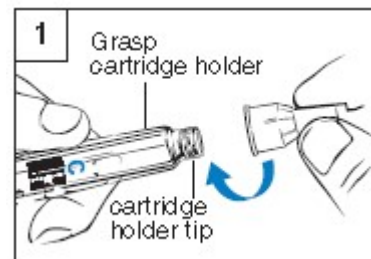
- Get training from your doctor or nurse.
- Know your dose. Know the pen parts.
- Make sure you have the pen with the blue injection button.
- Wash your hands.



Setting Up and Using a New GoQuick

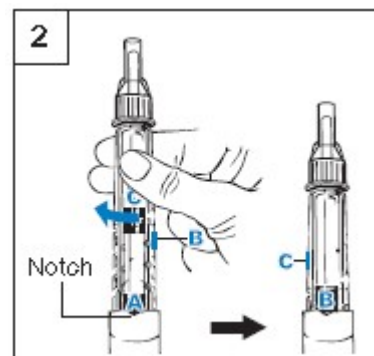
Step 1. Attach the Needle

- a. Pull the white pen cap straight off the pen.
- b. Peel the seal from a new needle.
- c. Firmly grasp the cartridge holder. (Figure 1)
- d. Push the needle onto the cartridge holder tip.
- e. Gently screw the needle onto the pen. Do not overtighten.
- f. Leave both needle covers on the needle.



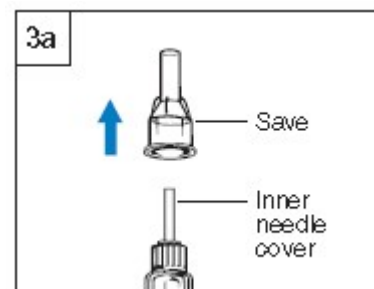
Step 2. Mix the Genotropin

- a. Hold the pen with the needle-end pointing up and the **A** facing you. (Figure 2)
- b. **Firmly** twist the cartridge holder into the pen until **B** clicks into the notch.
 - Gently tilt the pen from side to side. Do not shake the pen. Shaking may damage the growth hormone.
- c. Check that the liquid in the cartridge is clear. All the powder should be dissolved.
 - If not, gently tilt the pen from side to side a few more times.
- d. Check the liquid again. Make sure it is clear.
 - If the liquid is clear, go to Step 3.
 - If the liquid is still cloudy or you see any powder, use a new pen.

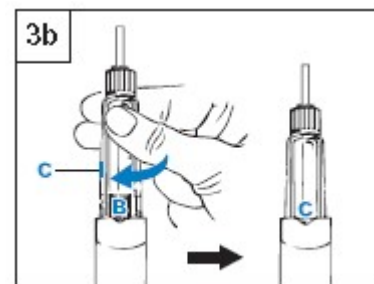


Step 3. Remove the Air

- a. Pull the outer needle cover off. Save it to re-cap the needle. (Figure 3a)
- b. Leave the inner needle cover on.

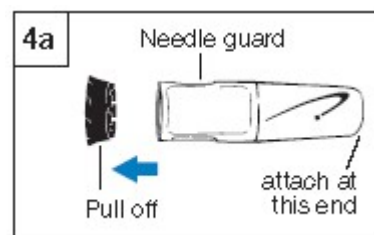


- c. Hold the pen with the needle-end pointing up. (Figure 3b)
- d. Tap the cartridge holder gently to help any trapped air move to the top.
- e. **Firmly**, twist the cartridge holder into the pen until **C** clicks into the notch.
 - Some liquid may appear around the inner needle cover.

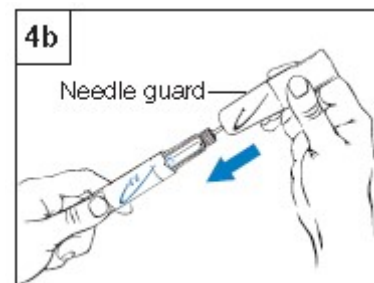


Step 4. Attach the Needle Guard (Optional)

- a. Pull the black cap off the needle guard. (Figure 4a)
 - If the needle shield slides out, push it back into the needle guard until it clicks into place.

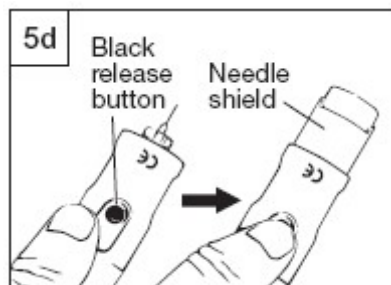
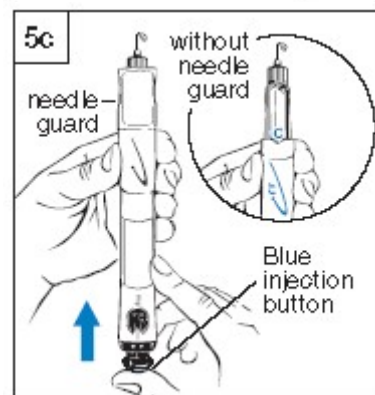
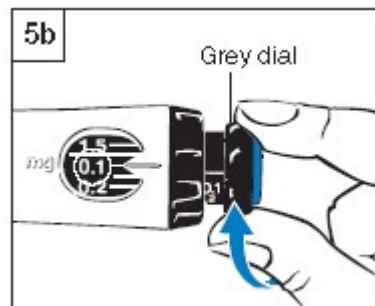
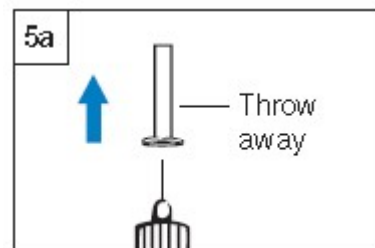


- b. Hold the pen in one hand below the blue logo. With the other hand, hold the needle guard below the needle shield. (Figure 4b)
- c. Line up the black logo on the needle guard with the blue logo on the pen. Carefully push the needle guard onto the pen until it snaps into place.



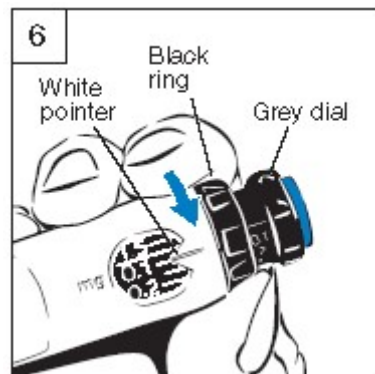
Step 5. Prime the Pen

- a. Pull the inner needle cover off. Throw it away. (Figure 5a)
- b. Check that 0.1 mg is set in the memory window.
- c. Turn the grey dial in the direction of the arrows until it stops clicking. (Figure 5b)
- d. Hold the pen with the needle pointing up. (Figure 5c with and without needle guard)
- e. Push the blue injection button until liquid appears.
- f. If liquid does not appear at Step “e”, repeat Steps b-e in this section up to two more times.
- g. If liquid still does not appear, do not use the pen.
 - See the Questions and Answers section below for more information.
- h. If you use the needle guard, press the black button to release the needle shield. (Figure 5d)



Step 6. Set the Dose

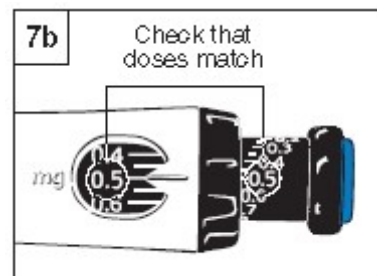
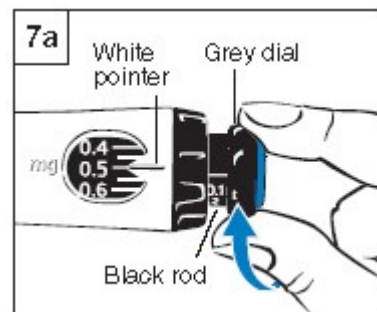
- Use the black ring to set the dose. Be careful not to turn the grey dial while setting the dose.
- a. Hold the black ring as shown in Figure 6.
 - b. Turn the black ring until your dose lines up with the white pointer. Your doctor or nurse has told you your dose.
 - c. If you turn your dose past the white pointer, just turn the black ring back to set the correct dose.
 - d. Once you have set your dose, do not change it unless your doctor or nurse tells you.



Note: If you cannot turn the black ring, press in the blue injection button until it stops clicking. Then continue to set your dose using the black ring (for more information, see also the Questions and Answers section below).

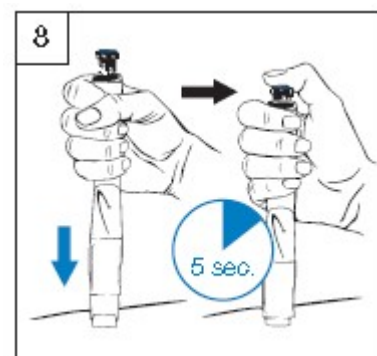
Step 7. Draw Up a Dose

- a. Turn the grey dial in the direction of the arrow until the clicking stops. (Figure 7a)
- b. Your dose on the black rod should line up with the white pointer.
- c. Check that the dose you drew up on the black rod is the same as the dose you set in the memory window. Figure 7b shows an example.
- d. If the doses do not match, make sure you have turned the grey dial in the direction of the arrow until it does not click anymore.



Step 8. Give the Injection

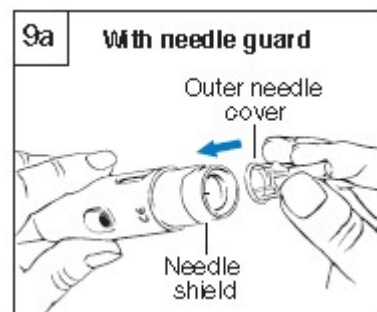
- a. Prepare an injection site as your doctor or nurse has told you.
- b. Hold the pen over the injection site.
- c. Push the pen down to insert the needle into the skin.
- d. Using your thumb, push the blue injection button down until it stops clicking. (Figure 8)
 - Count for 5 seconds before you pull the needle out of the skin. Keep light pressure on the button with your thumb while you count.
- e. Pull the pen straight out from the skin.



Step 9. Remove the Needle; Cap and Store Your Pen

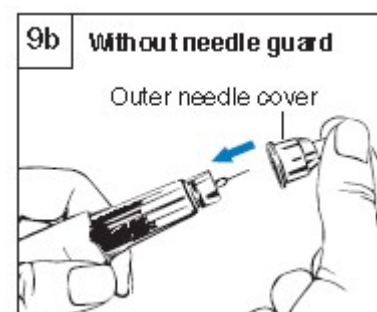
Step 9a: With needle guard

- a. Place the outer needle cover into the end of the needle shield. (Figure 9a)
- b. Use the needle cover to push in the needle shield until it locks into place.
- c. Use the needle cover to unscrew the needle and put it in a proper container for used needles.
- d. Leave the needle guard on the pen.
- e. Place the black cap on the needle guard. Store your pen in the refrigerator.



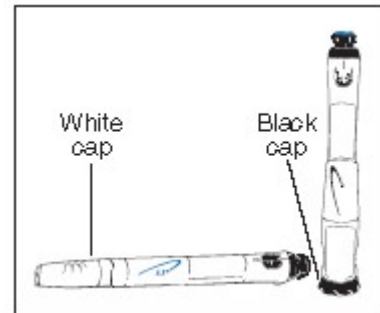
Step 9b: Without needle guard

- a. Do not touch the needle.
- b. Carefully cap the needle with the outer needle cover. (Figure 9b)
- c. Use the needle cover to unscrew the needle and put it in a proper container for used needles.
- d. Place the white cap on the pen. Store your pen in the refrigerator.

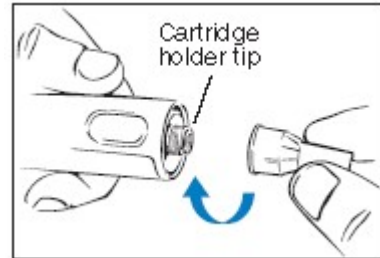


Routine Use of GoQuick

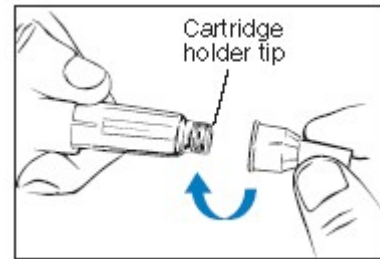
1. Pull the black cap from the needle guard or the white cap from the pen.



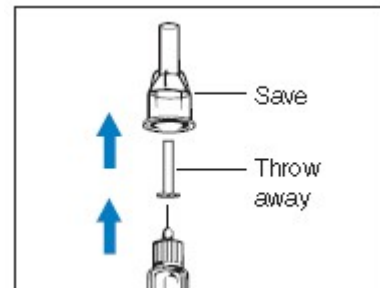
2. Attach a new needle.
 - With the needle guard:
 - If the needle shield releases, push it back into place.
 - Attach a new needle to the cartridge holder tip.



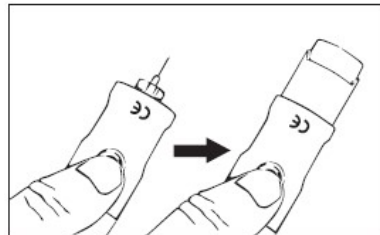
- Without the needle guard:
 - Attach a new needle to the cartridge holder tip.



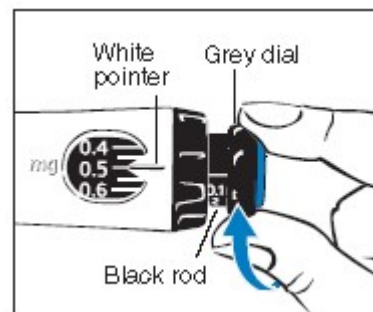
3. Remove both needle covers. Save the outer needle cover.



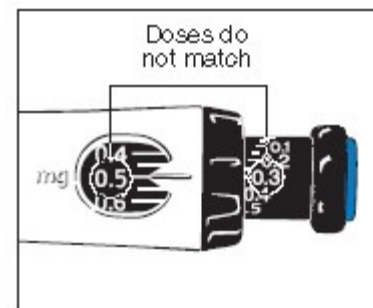
4. If you use the needle guard, press the black release button to extend the needle shield.



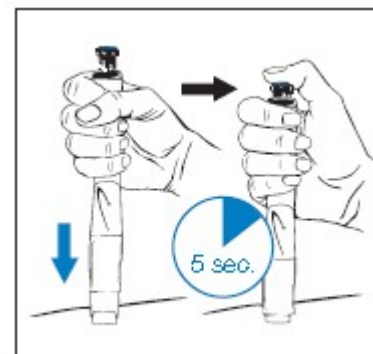
5. To draw up the dose, turn the grey dial until it stops clicking.



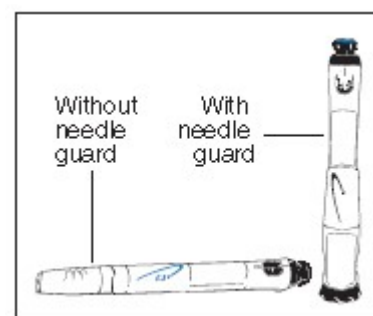
6. Check that the dose you drew up is the same as the dose you set in the memory window.
- If the dose you drew up is smaller, the pen does not have a full dose of Genotropin.
 - Follow what your doctor or nurse told you to do when the pen does not have a full dose left.



7. Prepare an injection site as your doctor or nurse has told you.
8. Give the injection.
- Push the pen down to insert the needle into the skin.
 - Push the blue injection button down until it stops clicking.
 - Count for 5 seconds before you pull the needle out of the skin. Keep light pressure on the button with your thumb while you count.
 - Pull the pen straight out from the skin.



9. Remove the needle.
- With the needle guard:
 - Use the outer needle cover to push in the needle shield until it locks into place.
 - Without the needle guard:
 - Carefully cap the needle with the outer needle cover.
 - Use the outer needle cover to unscrew the needle. Throw the needle away in a proper container for used needles.



10. Cap your needle guard or pen and store it in the refrigerator.

ADDITIONAL INFORMATION

Storage

- See the other side of this leaflet for how to store your GoQuick.
- After 4 weeks, dispose of the pen (or discard) even if there is some medicine left.
- Do not freeze or expose GoQuick to frost.
- Do not use your GoQuick after its expiry date.
- Follow your local health and safety laws to dispose of (or discard) your pen. Ask your doctor or nurse, if you are not sure what to do.

Handling

- Do not mix the powder and liquid of GoQuick unless a needle is on the pen.
- Do not store your GoQuick with the needle attached. The Genotropin may leak from the pen and air bubbles may form in the cartridge. Always remove the needle and attach the pen cap or needle guard cap before storing.
- Take care not to drop your GoQuick.
- If you do drop the pen you must perform another prime as described in Step 5 (Setting Up and Using a New GoQuick). But if any part of your GoQuick appears broken or damaged, do not use the pen. Contact your doctor or nurse for another pen.
- Clean the pen and needle guard with a damp cloth. Do not put the pen in water.

Needles

- Always use a new needle for each injection.
- Put all used needles in an appropriate “sharps” container. Follow your local health and safety laws to dispose of your needles. Ask your doctor or nurse, if you are not sure what to do.
- Do not share your pen or needles.

General

- The numbers and lines on the cartridge holder can help you estimate how much Genotropin is left in the pen.
- If in routine use Step 6 the pen does not have a full dose of Genotropin, the scale on the black rod indicates the amount of drug remaining in the pen.
- Patients who are blind or who do not see well should only use GoQuick with the help of someone trained to use the pen.
- Follow your doctor or nurse’s instructions for cleaning your hands and skin when you prepare and give the injection.
- Do not discard your needle guard, to remove it from the pen just twist it off. Save it to use with each new pen.
- If you have questions about how to use GoQuick, ask your doctor or nurse.

QUESTIONS AND ANSWERS

Question

What should I do if I see more than a small drop of liquid on the needle after giving my injection?

Answer

For your next injection wait the full time of 5 seconds before taking the needle from the skin. If you still see some liquid after you take out the needle, hold in for a little longer next time.

Is it a problem if I see air bubbles in the cartridge?

No, small amounts of air may be present in the cartridge during normal use.

What should I do if I see Genotropin leaking from the pen?

Make sure that the needle has been attached correctly.

What should I do if the pen that I am using was not put in the refrigerator overnight?

Discard the pen and use a new GoQuick.

What should I do if I can’t turn the black ring?

You have probably accidentally turned the grey dial. If you have turned the grey dial the pen will prevent you from turning the black ring so that your dose does not change during your injection.

To release the black ring, press in the blue injection button until it stops. Note that liquid will come out of the needle. Then continue to set your dose using the black ring.

What if my doctor changes my dose when I’ve already started a pen?

Set the new dose by turning the black ring.

What if I inject the wrong dose?

Call your doctor or nurse immediately and follow his/her instructions.

What if my pen will not prime (i.e. if liquid did not appear in step 5g)?

Call your doctor or nurse and follow his/her instructions.

What doses can my pen deliver?

The pen can deliver doses from 0.10mg to 1.5mg of Genotropin. Each click of the black ring changes the dose by 0.05mg.

GENOTROPIN®GOQUICK™ 12

INSTRUCTIONS FOR USE

Important Information

Please read these instructions completely before using GoQuick.

If you have any questions about your dose or your treatment with Genotropin, call your doctor or nurse.

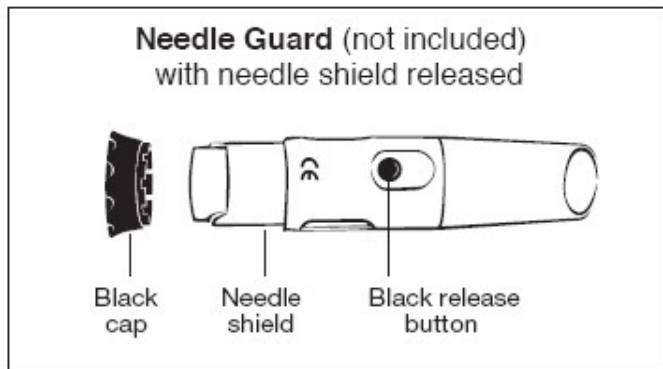
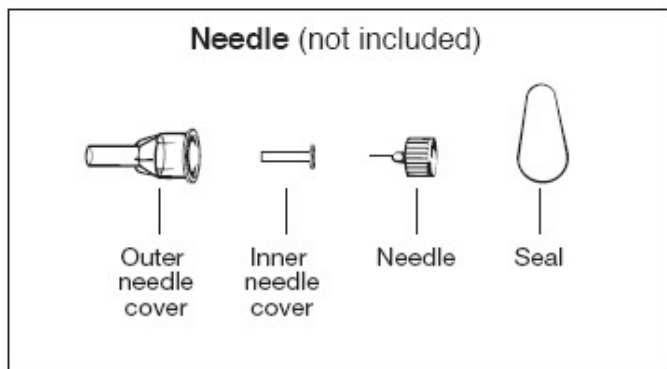
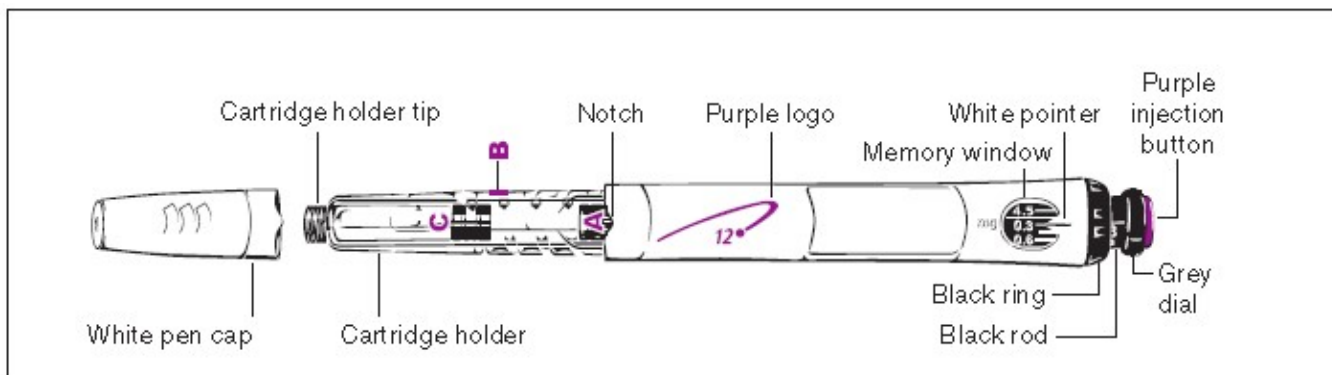
About GoQuick

GoQuick is a prefilled, multidose, disposable injection pen that holds 12 mg of somatropin. After reconstitution the concentration of somatropin is 12 mg per mL. The Genotropin in the pen is mixed only once, when you start a new pen. A single pen can be used for up to 28 days after mixing. You never have to change cartridges. When the pen is empty, you just start a new pen.

The pen has dose memory. The dose is set once on a new pen. The pen then gives the same dose for each injection. You can use the pen with or without the optional needle guard.

Before You Use GoQuick

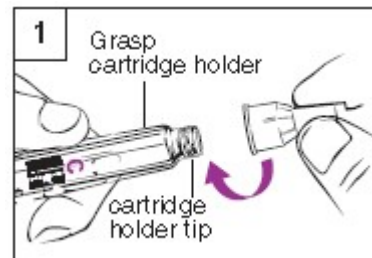
- Get training from your doctor or nurse.
- Know your dose. Know the pen parts.
- Make sure you have the pen with the purple injection button.
- Wash your hands.



Setting Up and Using a New GoQuick

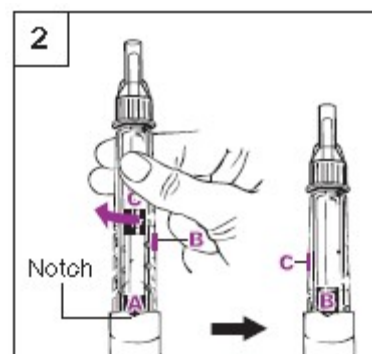
Step 1. Attach the Needle

- a. Pull the white pen cap straight off the pen.
- b. Peel the seal from a new needle.
- c. Firmly grasp the cartridge holder. (Figure 1)
- d. Push the needle onto the cartridge holder tip.
- e. Gently screw the needle onto the pen. Do not overtighten.
- f. Leave both needle covers on the needle.



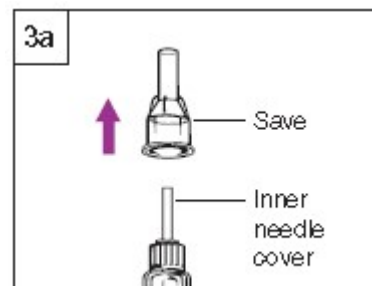
Step 2. Mix the Genotropin

- a. Hold the pen with the needle-end pointing up and the **A** facing you. (Figure 2)
- b. **Firmly** twist the cartridge holder into the pen until **B** clicks into the notch.
 - Gently tilt the pen from side to side. Do not shake the pen. Shaking may damage the growth hormone.
- c. Check that the liquid in the cartridge is clear. All the powder should be dissolved.
 - If not, gently tilt the pen from side to side a few more times.
- d. Check the liquid again. Make sure it is clear.
 - If the liquid is clear, go to Step 3.
 - If the liquid is still cloudy or you see any powder, use a new pen.

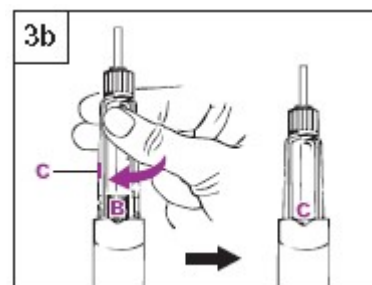


Step 3. Remove the Air

- a. Pull the outer needle cover off. Save it to re-cap the needle. (Figure 3a)
- b. Leave the inner needle cover on.

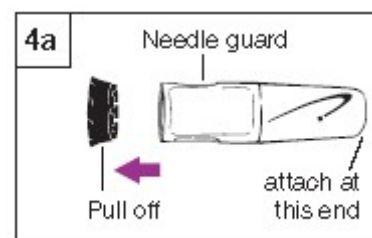


- c. Hold the pen with the needle-end pointing up. (Figure 3b)
- d. Tap the cartridge holder gently to help any trapped air move to the top.
- e. **Firmly**, twist the cartridge holder into the pen until **C** clicks into the notch.
 - Some liquid may appear around the inner needle cover.

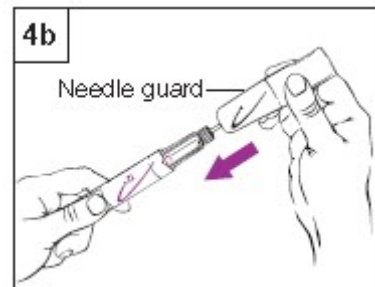


Step 4. Attach the Needle Guard (Optional)

- a. Pull the black cap off the needle guard. (Figure 4a)
 - If the needle shield slides out, push it back into the needle guard until it clicks into place.

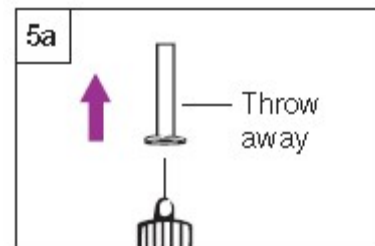


- b. Hold the pen in one hand below the purple logo. With the other hand, hold the needle guard below the needle shield. (Figure 4b)
- c. Line up the black logo on the needle guard with the purple logo on the pen. Carefully push the needle guard onto the pen until it snaps into place.

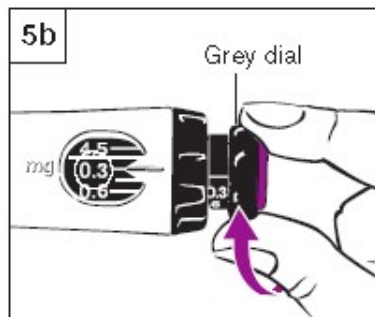


Step 5. Prime the Pen

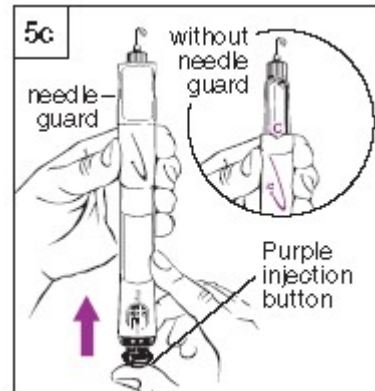
- a. Pull the inner needle cover off. Throw it away. (Figure 5a)



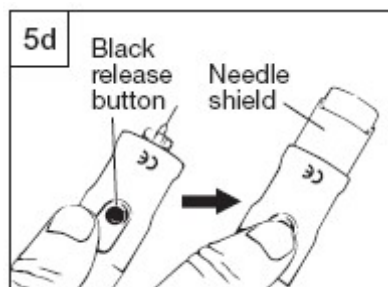
- b. Check that 0.3 mg is set in the memory window.
- c. Turn the grey dial in the direction of the arrows until it stops clicking. (Figure 5b)



- d. Hold the pen with the needle pointing up. (Figure 5c with and without needle guard)
- e. Push the purple injection button until liquid appears.
- f. If liquid does not appear at Step “e”, repeat Steps b-e in this section up to two more times.
- g. If liquid still does not appear, do not use the pen.
 - See the Questions and Answers section below for more information.



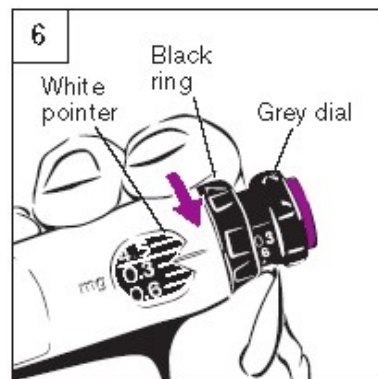
- h. If you use the needle guard, press the black button to release the needle shield. (Figure 5d)



Step 6. Set the Dose

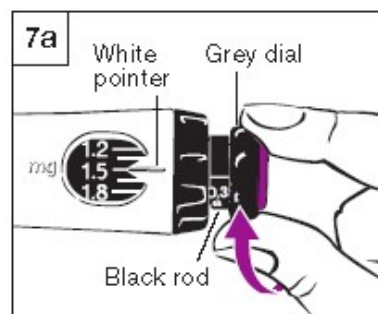
- Use the black ring to set the dose. Be careful not to turn the grey dial while setting the dose.
- a. Hold the black ring as shown in Figure 6.
- b. Turn the black ring until your dose lines up with the white pointer. Your doctor or nurse has told you your dose.
- c. If you turn your dose past the white pointer, just turn the black ring back to set the correct dose.
- d. Once you have set your dose, do not change it unless your doctor or nurse tells you.

Note: If you cannot turn the black ring, press in the purple injection button until it stops clicking. Then continue to set your dose using the black ring (for more information, see also the Questions and Answers section below).

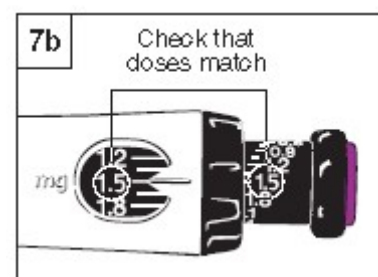


Step 7. Draw Up a Dose

- a. Turn the grey dial in the direction of the arrow until the clicking stops. (Figure 7a)
- b. Your dose on the black rod should line up with the white pointer.

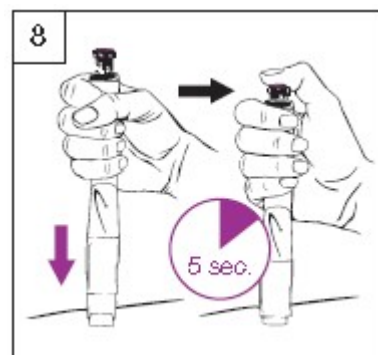


- c. Check that the dose you drew up on the black rod is the same as the dose you set in the memory window. Figure 7b shows an example.
- d. If the doses do not match, make sure you have turned the grey dial in the direction of the arrow until it does not click anymore.



Step 8. Give the Injection

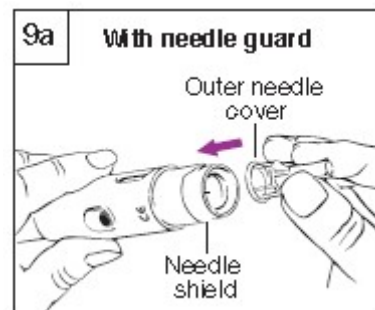
- a. Prepare an injection site as your doctor or nurse has told you.
- b. Hold the pen over the injection site.
- c. Push the pen down to insert the needle into the skin.
- d. Using your thumb, push the purple injection button down until it stops clicking. (Figure 8)
 - Count for 5 seconds before you pull the needle out of the skin. Keep light pressure on the button with your thumb while you count.
- e. Pull the pen straight out from the skin.



Step 9. Remove the Needle; Cap and Store Your Pen

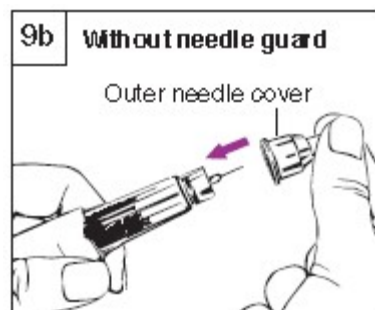
Step 9a: With needle guard

- a. Place the outer needle cover into the end of the needle shield. (Figure 9a)
- b. Use the needle cover to push in the needle shield until it locks into place.
- c. Use the needle cover to unscrew the needle and put it in a proper container for used needles.
- d. Leave the needle guard on the pen.
- e. Place the black cap on the needle guard. Store your pen in the refrigerator.



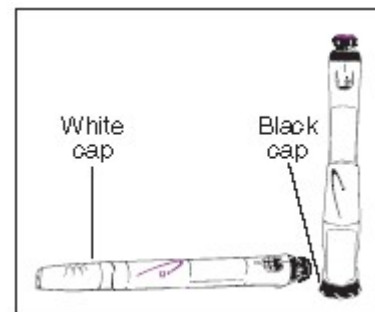
Step 9b: Without needle guard

- a. Do not touch the needle.
- b. Carefully cap the needle with the outer needle cover. (Figure 9b)
- c. Use the needle cover to unscrew the needle and put it in a proper container for used needles.
- d. Place the white cap on the pen. Store your pen in the refrigerator.



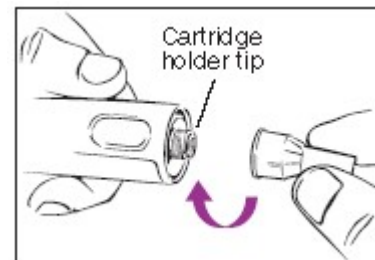
Routine Use of GoQuick

1. Pull the black cap from the needle guard or the white cap from the pen.

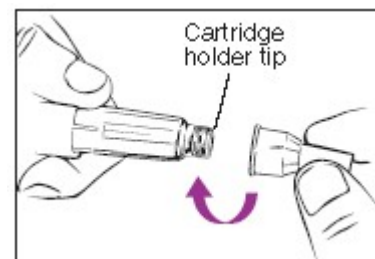


2. Attach a new needle.

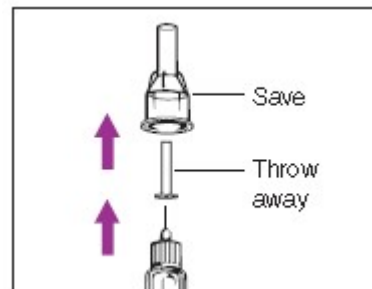
- With the needle guard:
 - If the needle shield releases, push it back into place.
 - Attach a new needle to the cartridge holder tip.



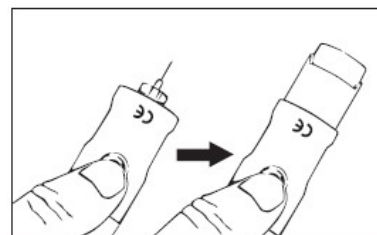
- Without the needle guard:
 - Attach a new needle to the cartridge holder tip.



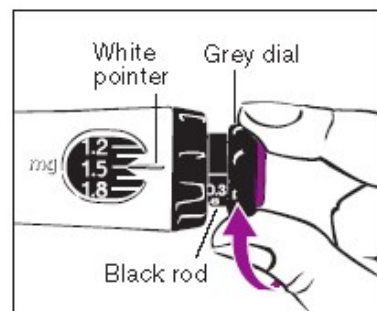
3. Remove both needle covers. Save the outer needle cover.



4. If you use the needle guard, press the black release button to extend the needle shield.

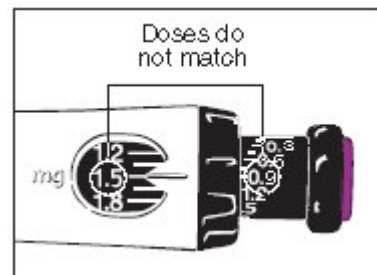


5. To draw up the dose, turn the grey dial until it stops clicking.



6. Check that the dose you drew up is the same as the dose you set in the memory window.

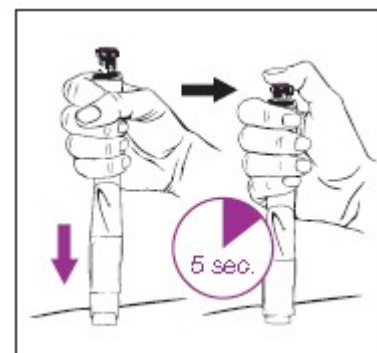
- If the dose you drew up is smaller, the pen does not have a full dose of Genotropin.
- Follow what your doctor or nurse told you to do when the pen does not have a full dose left.



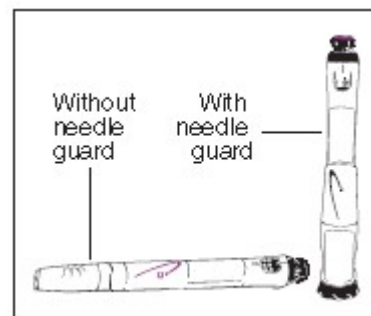
7. Prepare an injection site as your doctor or nurse has told you.

8. Give the injection.

- Push the pen down to insert the needle into the skin.
- Push the purple injection button down until it stops clicking.
- Count for 5 seconds before you pull the needle out of the skin. Keep light pressure on the button with your thumb while you count.
- Pull the pen straight out from the skin.



9. Remove the needle.
 - With the needle guard:
 - Use the outer needle cover to push in the needle shield until it locks into place.
 - Without the needle guard:
 - Carefully cap the needle with the outer needle cover.
 - Use the outer needle cover to unscrew the needle. Throw the needle away in a proper container for used needles.
10. Cap your needle guard or pen and store it in the refrigerator.



ADDITIONAL INFORMATION

Storage

- See the other side of this leaflet for how to store your GoQuick.
- After 4 weeks, dispose of the pen (or discard) even if there is some medicine left.
- Do not freeze or expose GoQuick to frost.
- Do not use your GoQuick after its expiry date.
- Follow your local health and safety laws to dispose of (or discard) your pen. Ask your doctor or nurse, if you are not sure what to do.

Handling

- Do not mix the powder and liquid of GoQuick unless a needle is on the pen.
- Do not store your GoQuick with the needle attached. The Genotropin may leak from the pen and air bubbles may form in the cartridge. Always remove the needle and attach the pen cap or needle guard cap before storing.
- Take care not to drop your GoQuick.
- If you do drop the pen you must perform another prime as described in Step 5 (Setting Up and Using a New GoQuick). But if any part of your GoQuick appears broken or damaged, do not use the pen. Contact your doctor or nurse for another pen.
- Clean the pen and needle guard with a damp cloth. Do not put the pen in water.

Needles

- Always use a new needle for each injection.
- Put all used needles in an appropriate “sharps” container. Follow your local health and safety laws to dispose of your needles. Ask your doctor or nurse, if you are not sure what to do.
- Do not share your pen or needles.

General

- The numbers and lines on the cartridge holder can help you estimate how much Genotropin is left in the pen.
- If in routine use Step 6 the pen does not have a full dose of Genotropin, the scale on the black rod indicates the amount of drug remaining in the pen.
- Patients who are blind or who do not see well should only use GoQuick with the help of someone trained to use the pen.
- Follow your doctor or nurse’s instructions for cleaning your hands and skin when you prepare and give the injection.
- Do not discard your needle guard, to remove it from the pen just twist it off. Save it to use with each new pen.
- If you have questions about how to use GoQuick, ask your doctor or nurse.

QUESTIONS AND ANSWERS

Question

What should I do if I see more than a small drop of liquid on the needle after giving my injection?

Answer

For your next injection wait the full time of 5 seconds before taking the needle from the skin. If you still see some liquid after you take out the needle, hold in for a little longer next time.

Is it a problem if I see air bubbles in the cartridge?

No, small amounts of air may be present in the cartridge during normal use.

What should I do if I see Genotropin leaking from the pen?

Make sure that the needle has been attached correctly.

What should I do if the pen that I am using was not put in the refrigerator overnight?

Discard the pen and use a new GoQuick.

What should I do if I can't turn the black ring?

You have probably accidentally turned the grey dial. If you have turned the grey dial the pen will prevent you from turning the black ring so that your dose does not change during your injection.

To release the black ring, press in the purple injection button until it stops. Note that liquid will come out of the needle. Then continue to set your dose using the black ring.

What if my doctor changes my dose when I've already started a pen?

Set the new dose by turning the black ring.

What if I inject the wrong dose?

Call your doctor or nurse immediately and follow his/her instructions.

What if my pen will not prime (i.e. if liquid did not appear in step 5g)?

Call your doctor or nurse and follow his/her instructions.

What doses can my pen deliver?

The pen can deliver doses from 0.30 mg to 4.5 mg of Genotropin. Each click of the black ring changes the dose by 0.15 mg.