

GENOTROPIN[®]

Somatropin (5.3 mg, 12 mg)

What is in this leaflet

1. What GENOTROPIN is used for
2. How GENOTROPIN works
3. Before you use GENOTROPIN
4. How to use GENOTROPIN
5. While you are using it
6. Side Effects
7. Storage and Disposal of GENOTROPIN
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision
11. Serial Number

What GENOTROPIN is used for

In children, GENOTROPIN is used to treat growth disturbances:

- If you do not have enough of your own growth hormone.
- If you have Turner syndrome (chromosomal error in girls that can affect growth).
- If you have chronic renal (kidney) insufficiency. As kidneys lose their ability to function normally, this can affect growth.
- If you have Prader-Willi syndrome (a chromosomal disorder). Growth hormone will help you grow taller if you are still growing, and will also improve your body composition.
- If you were small or too light at birth or if you have not been able to catch up or maintain normal growth by four years of age or later.

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.

How GENOTROPIN works

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. It is a recombinant DNA-derived protein, meaning it is not made from human or animal tissue.

Before you use GENOTROPIN**- When you must not use it**

Do not take GENOTROPIN if

- You are allergic (hypersensitive) to somatropin or any of the other ingredients of GENOTROPIN (listed under Product Description).
- You have an active tumour (cancer). Tumours must be inactive and you must have finished your anti-tumour treatment before you start your treatment with GENOTROPIN.
- You are seriously ill (for example, complications following open heart surgery, abdominal surgery, acute respiratory failure, accidental injury or similar conditions).
- Children who have already stopped growing (closed epiphyses).

Pregnancy and lactation

You should not use GENOTROPIN if you are pregnant, or if you have childbearing potential but are not using contraception.

Ask your doctor for advice before using this medicine while breast-feeding.

- Before you start to use it

Talk to your doctor before taking GENOTROPIN:

- If you are receiving GENOTROPIN and thyroid hormone replacement therapy concurrently, your doctor will need to monitor your thyroid function closely.
- If you are diabetic and are receiving insulin therapy,

GENOTROPIN may reduce your insulin sensitivity, tell your doctor. Your dose of insulin may need to be adjusted after GENOTROPIN is initiated.

- If you have severe or reoccurring headache, eye problems, vomiting and nausea, your doctor may examine your eyes to assess if you have increased pressure around your skull. Based on this examination, your doctor will determine whether or not to continue treatment with GENOTROPIN.
- If you are receiving GENOTROPIN therapy, you may be at risk of reduced cortisol levels (stress hormone) in your blood due to underactivity of your adrenal glands and may require steroids. If you were previously diagnosed with underactive adrenal gland, your doctor may need to adjust your steroid dose.
- If you are taking GENOTROPIN and oral oestrogen therapy concurrently, your doctor may need to adjust the dose of GENOTROPIN
- If you had cancer in childhood, there is an increased chance of getting tumours again after treatment with GENOTROPIN.
- Experience in people above 80 years of age is limited. Elderly persons may be more sensitive to the action of GENOTROPIN and therefore may be more prone to develop side effects.
- If you are suffering from any other critical illness, your doctor will decide on whether this medicine is suitable for you or not by weighing the possible benefit against the potential risk involved.

Children with Prader-Willi syndrome:

- Your doctor will give you diet restrictions to follow to ensure effective weight control before

GENOTROPIN[®]

Somatropin (5.3 mg, 12 mg)

and during treatment with GENOTROPIN.

- Your doctor will assess you for signs of upper airway obstruction, sleep apnoea (where your breathing is interrupted during sleep), or respiratory infection before you start treatment with GENOTROPIN.
- During treatment, if you show signs of upper airway obstruction (including starting to snore or worsening of snoring), your doctor will refer you to an Ear, Nose and Throat (ENT) specialist for an assessment and your treatment with GENOTROPIN may be interrupted.
- During treatment, your doctor will check you for signs of scoliosis, a type of spinal deformity that might happen during rapid growth.
- During treatment, if you develop a lung infection, tell your doctor so that he can treat the infection.

Children with chronic renal (kidney) insufficiency:

- Your doctor should examine your kidney function and verify your growth disturbance by following your growth for a year before starting GENOTROPIN. Medical treatment for your kidney condition should be maintained throughout. GENOTROPIN treatment should be stopped at kidney transplantation.

Children born small or too light at birth:

- Your doctor will check your blood sugar and insulin levels before the start of treatment and every year during treatment.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or

health food shop. Some medicines when taken with GENOTROPIN may cause GENOTROPIN to be less effective and *vice versa*.

You should inform your doctor if you are taking

- medicines to treat diabetes,
- thyroid hormones,
- steroids to reduce inflammation (corticosteroids),
- sex hormones (for example, oestrogens),
- ciclosporin (a medicine that weakens the immune system after transplantation),
- medicines to control epilepsy (anticonvulsants).

How to use GENOTROPIN

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

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) or your body surface area calculated from your height and weight in square metres (m²), as well as your treatment schedule. Do not change the dosage and treatment schedule without consulting your doctor.

Children with growth hormone deficiency:

0.025-0.035 mg/kg body weight per day or 0.7-1.0 mg/m² body surface area per day. 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: 0.045-0.050 mg/kg body weight per day or 1.4 mg/m² body surface area per day.

Children with chronic renal (kidney) insufficiency: 0.045-0.050 mg/kg body weight per day or 1.4 mg/m² body surface area per day). Higher doses may be necessary if the rate of growth is too low. Dosage adjustment may be necessary after 6 months of treatment.

Children with Prader-Willi syndrome:

0.035 mg/kg body weight per day or 1.0 mg/m² body surface area per day. The daily dosage should not exceed 2.7 mg. Treatment should not be used in children who have almost stopped growing after puberty.

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

0.035 mg/kg body weight per day or 1.0 mg/m² body surface area per day). It is important to continue treatment until final height is reached. Treatment should be discontinued after the first year if you are not responding or if you have reached your final height and stopped growing.

Adults with growth hormone deficiency:

- If you continue GENOTROPIN after treatment during childhood you should start with 0.2-0.5 mg per day.
- If your growth hormone deficiency starts during adult life you should start with 0.15-0.3 mg per day.
- This dosage should be gradually increased according to blood test

GENOTROPIN[®]

Somatropin (5.3 mg, 12 mg)

results as well as clinical response and side effects.

The daily maintenance dose seldom exceeds 1.0 mg per day. Women may require higher doses than men. Dosage should be monitored every 6 months.

Persons above 60 years should start with a dose of 0.1–0.2 mg per day which should be slowly increased according to individual requirements. The minimum effective dose should be used.

The maintenance dose seldom exceeds 0.5 mg per day. Follow the instructions given to you by your doctor.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking GENOTROPIN for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Inject the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not inject a double dose to make up for the missed dose.

- If you use too much (overdose)

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.

While you are using it- Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking GENOTROPIN.
- Tell your doctor immediately if you become pregnant while taking this medication.
- If you are receiving GENOTROPIN for growth hormone deficiency following a previous tumour (cancer), you should be examined regularly for recurrence of the tumour.
- If you have diabetes, you should closely monitor your blood sugar level during treatment with GENOTROPIN and discuss the results with your doctor to determine whether you need to change the dose of your medicines to treat diabetes.
- Tell your doctor if you are taking growth hormone to stimulate growth and walk with a limp, or if you start to limp during your growth hormone treatment due to pain in your hip.
- If your doctor confirms that you have developed muscle pain or disproportionate pain near the injection site because of the preservative metacresol, you should use a GENOTROPIN product without metacresol.
- Tell your doctor if you develop stomach pain during the treatment with GENOTROPIN. It may be due to inflammation of the pancreas.

Injecting GENOTROPIN:

Refer to appendix 1 to find instructions for use.

- Things you must not do

- Do not stop taking the medicine unless advised by your doctor.

- Do not take any new medicines without consulting your doctor.
- Do not inject GENOTROPIN to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

When you are mixing GENOTROPIN, do not shake the solution. Mix it gently. Shaking the solution could make the growth hormone foam and damage the active substance.

Driving and using machines

No effects on the ability to drive and use machines have been observed.

Side Effects

Like all medicines, GENOTROPIN can cause side effects, although not everybody gets them. Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

In children with growth hormone deficiency:

Very common side effects:

- temporary reactions at the injection site

In children with Turner syndrome:

Very common side effects:

- joint pain

In children with chronic renal insufficiency:

Common side effects:

- temporary reactions at the injection site
- skin rash

In children with growth disturbance due to born small for gestational age:

Common side effects:

- temporary reactions at the injection site
- skin rash
- red, raised, itchy skin rash (hives)

GENOTROPIN®

Somatropin (5.3 mg, 12 mg)

In children with Prader-Willi syndrome:

Common side effects:

- tingling or pricking sensation
- increased pressure inside the skull
- muscle pain
- joint pain
- water retention (which shows as puffiness) at the legs
- skin rash

In adults with growth hormone deficiency:

Very common side effects:

- joint pain
- water retention (which shows as puffiness) at the legs

Common side effects:

- numbness/tingling of hand
- an abnormal sensation of tingling or pricking
- muscle stiffness, muscle pain

These symptoms may be seen for the first months of treatment, but they disappear spontaneously or when the dosage is lowered.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of GENOTROPIN**- Storage**

Before reconstitution:

Store in a refrigerator (2°C – 8°C), or for a maximum of 1 month at or below 25°C. Keep the pre-filled pen in the outer carton in order to protect from light.

After reconstitution:

Store in a refrigerator (2°C – 8°C). Do not freeze. Keep the pre-filled pen in the outer carton in order to protect from light.

From a microbiological point of view, once reconstituted, the

product may be stored for 4 weeks at 2°C - 8°C. Other in-use storage times and conditions are the responsibility of the user.

- Disposal

Any unused product or waste material should be disposed of in accordance with local requirements. Empty GoQuick pre-filled pens should never be refilled and must be properly discarded.

Product Description**- What it looks like**

Two-chamber cartridge: Powder and solvent for solution for injection. In the two-chamber cartridge there is a white powder in the front compartment and a clear solution in the rear compartment. The two-chamber cartridge is supplied for use in a disposable multidose pre-filled pen (GoQuick).

Powder and 1 ml solvent in a two-chamber glass cartridge (type I glass) separated by a rubber plunger (bromobutyl). The cartridge is sealed at one end with a rubber disc (bromobutyl) and an aluminium cap and at the other end by a rubber stopper (bromobutyl). The two-chamber cartridge is supplied in a sealed disposable multidose pre-filled pen, GoQuick.

The 5.3 mg pre-filled pen GoQuick is colour coded blue. The 12 mg pre-filled pen GoQuick is colour coded purple.

- Ingredients

- Active ingredient:
Somatropin

- Inactive ingredients:

Front compartment (powder):

Glycine

Mannitol
Sodium dihydrogen phosphate, monohydrate
Disodium phosphate, dodecahydrate

Rear compartment (solvent):

Water for injections
Metacresol
Mannitol

- MAL number(s)

Genotropin 5.3 mg powder and solvent for solution for injection-MAL20081840AZ

Genotropin 12 mg powder and solvent for solution for injection-MAL20081841AZ

Manufacturer

Pfizer Manufacturing Belgium N.V.
Rijksweg 12
Puurs B-2870
Belgium

Product Registration Holder

Pfizer (Malaysia) Sdn. Bhd.
Level 10 & 11
Wisma Averis, Tower 2
Avenue 5, Bangsar South
No. 8, Jalan Kerinchi
59200 Kuala Lumpur, Malaysia

Date of Revision

13/09/2021

Serial Number:

NPRA(R3/01)01092021/0142

PLD-GENOTROPIN-0921

GENOTROPIN[®]

Somatropin (5.3 mg, 12 mg)

GENOTROPIN[®]

Somatropin (5.3 mg, 12 mg)

APPENDIX 1**GOQUICK[®] INSTRUCTIONS FOR USE: 5.3 mg****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.

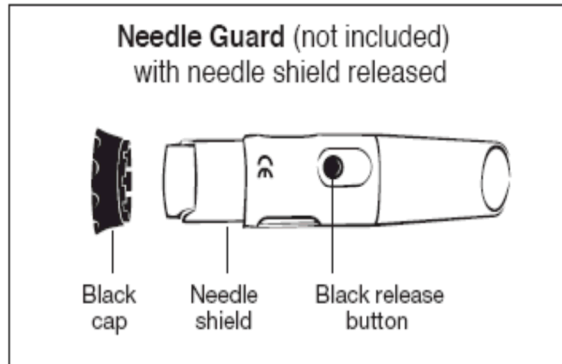
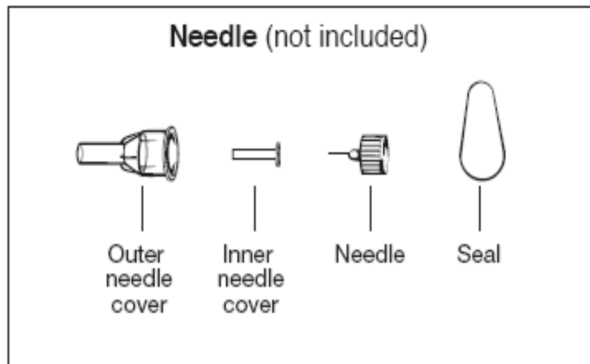
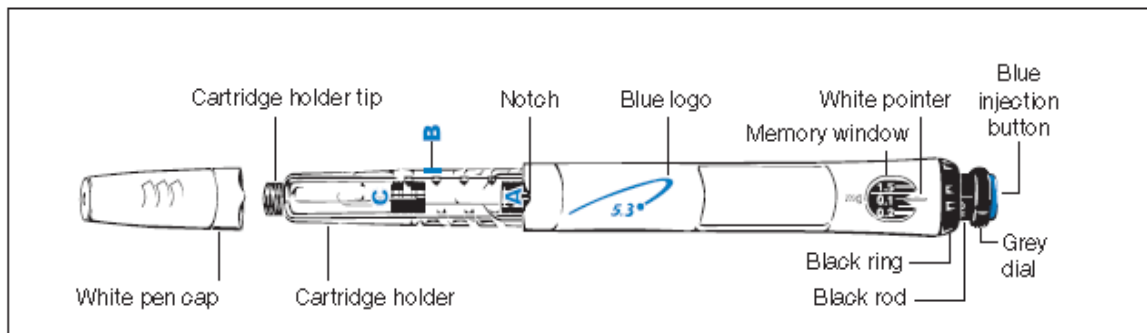
About GoQuick

GoQuick is a prefilled, multidose, disposable injection pen that holds 5.3 mg of somatropin. 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 blue injection button.
- Wash your hands.

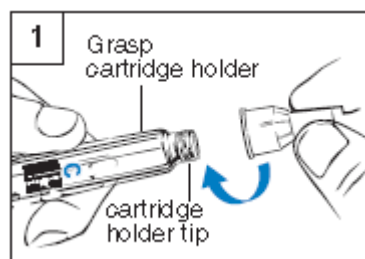


GENOTROPIN[®]

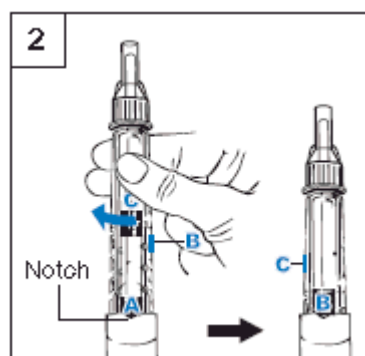
Somatotropin (5.3 mg, 12 mg)

Setting Up and Using a New GoQuick**Step 1. Attach the Needle**

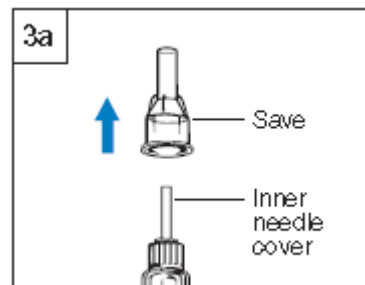
- Pull the white pen cap straight off the pen.
- Peel the seal from a new needle.
- Firmly grasp the cartridge holder. (Figure 1)
- Push the needle onto the cartridge holder tip.
- Gently screw the needle onto the pen. Do not overtighten.
- Leave both needle covers on the needle.

**Step 2. Mix the GENOTROPIN**

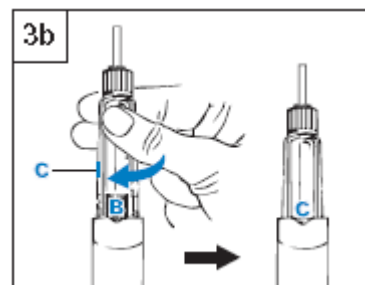
- Hold the pen with the needle-end pointing up and the A facing you. (Figure 2)
- Firmly** twist the cartridge holder into the pen until B clicks into the notch.
 - Gently tilt the pen from side to side. Do not shake the pen. Shaking may damage the growth hormone.
- Check that the liquid in the cartridge 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 remove 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.

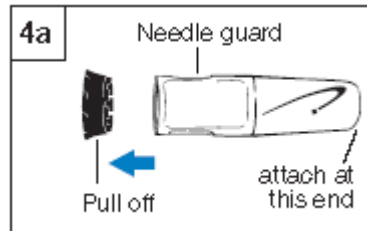


GENOTROPIN[®]

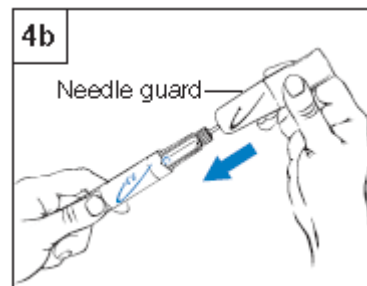
Somatropin (5.3 mg, 12 mg)

Step 4. Attach the Needle Guard (Optional)

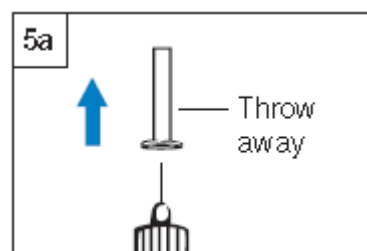
- a. Pull the black cap off the needle guard. (Figure 4a)
- If the needle shield slides out, push it back into the needle guard until it clicks into place.



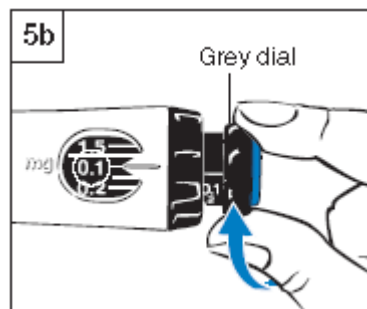
- b. Hold the pen in one hand below the blue logo. With the other hand, hold the needle guard below the needle shield. (Figure 4b)
- c. Line up the black logo on the needle guard with the blue logo on the pen. Carefully push the needle guard onto the pen until it snaps into place.

**Step 5. Prime the Pen**

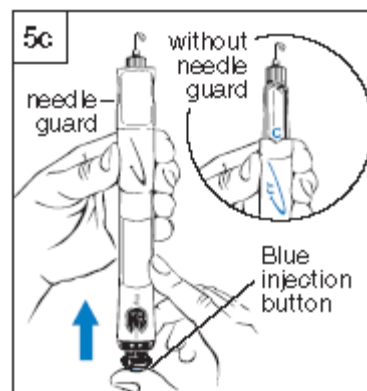
- a. Pull the inner needle cover off. Throw it away. (Figure 5a)



- 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)



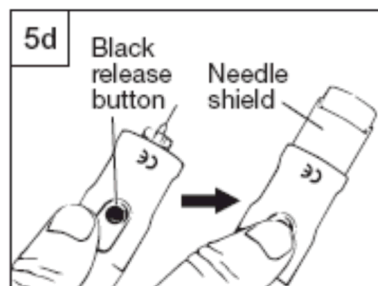
- d. Hold the pen with the needle pointing up. (Figure 5c with and without needle guard)
- e. Push the blue injection button until liquid appears.
- f. If liquid does not appear at Step “e”, repeat Steps b-e in this section up to two more times.
- g. If liquid still does not appear, do not use the pen.



GENOTROPIN[®]

Somatropin (5.3 mg, 12 mg)

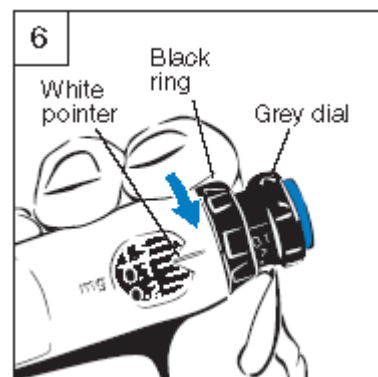
- h. If you use the needle guard, press the black button to release the needle shield. (Figure 5d)

**Step 6. Set the Dose**

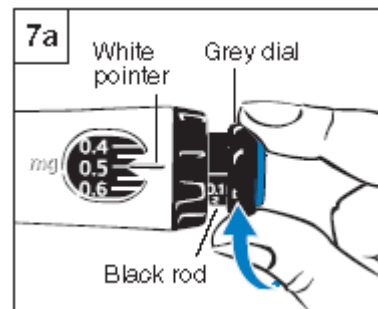
- Use the black ring to set the dose. Be careful not to turn the grey dial while setting the dose.

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

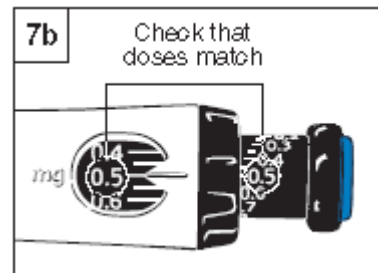
Note: If you cannot turn the black ring, press in the blue injection button until it stops clicking. Then continue to set your dose using the black ring.

**Step 7. Draw Up a Dose**

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



- 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.
- 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.

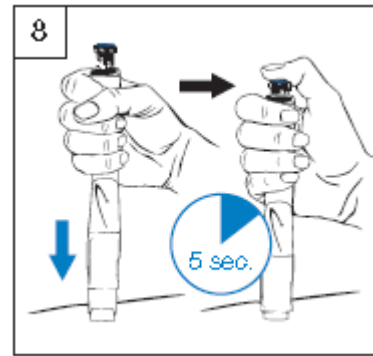


GENOTROPIN[®]

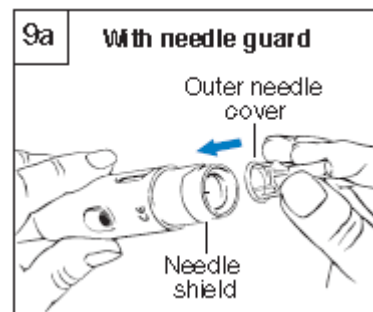
Somatropin (5.3 mg, 12 mg)

Step 8. Give the Injection

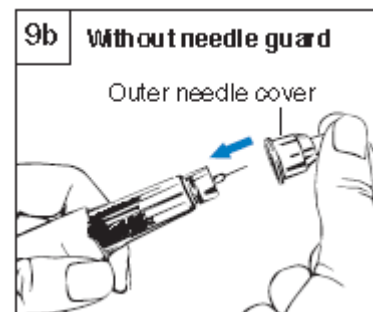
- a. Prepare an injection site as your doctor or nurse has told you.
- b. Hold the pen over the injection site.
- c. Push the pen down to insert the needle into the skin.
- d. Using your thumb, push the blue injection button down until it stops clicking. (Figure 8)
 - Count for 5 seconds before you pull 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**

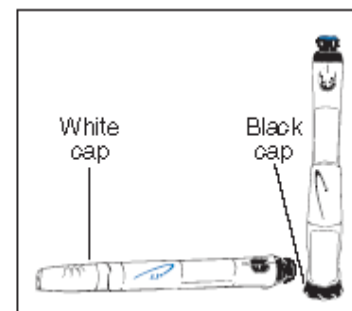
- a. Place the outer needle cover into the end of the needle shield. (Figure 9a)
- b. Use the needle cover to push in the needle shield until it locks into place.
- c. Use the needle cover to unscrew the needle and put it in a proper container for used needles.
- d. Leave the needle guard on the pen.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

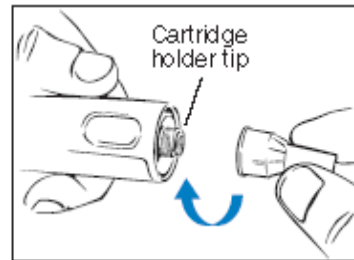
1. Pull the black cap from the needle guard or the white cap from the pen.



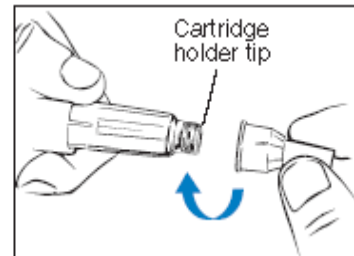
GENOTROPIN[®]

Somatropin (5.3 mg, 12 mg)

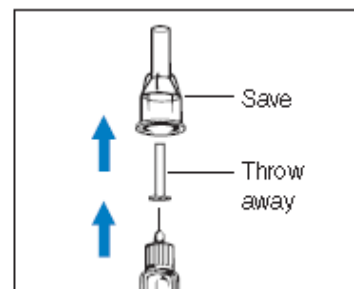
2. Attach a new needle.
 - With the needle guard:
 - If the needle shield releases, push it back into place.
 - Attach a new needle to the cartridge holder tip.



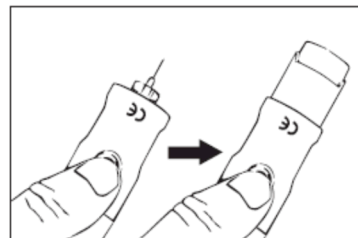
- Without the needle guard:
 - Attach a new needle to the cartridge holder tip.



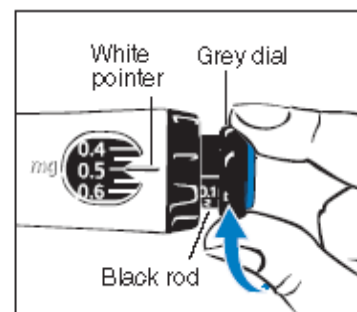
3. Remove both needle covers. Save the outer needle cover to remove the needle.



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



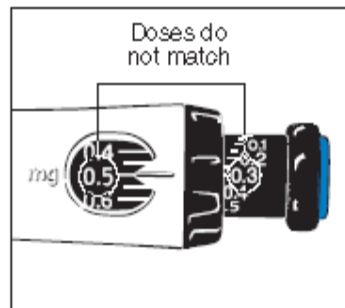
5. To draw up the dose, turn the grey dial until it stops clicking.



GENOTROPIN[®]

Somatropin (5.3 mg, 12 mg)

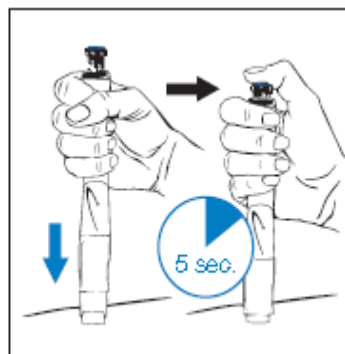
6. Check that the dose you drew up is the same as the dose you set in the memory window.
- If the dose you drew up is smaller, the pen does not have a full dose of GENOTROPIN.
 - Follow what your doctor or nurse told you to do when the pen does not have a full dose left.



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

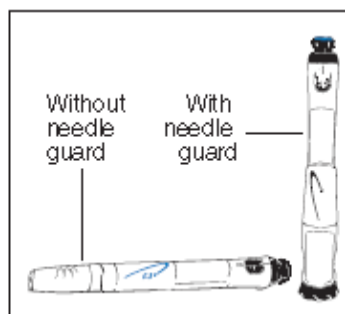
8. Give the injection.

- 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 cover 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.

GOQUICK[®] INSTRUCTIONS FOR USE: 12 mg**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. 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.

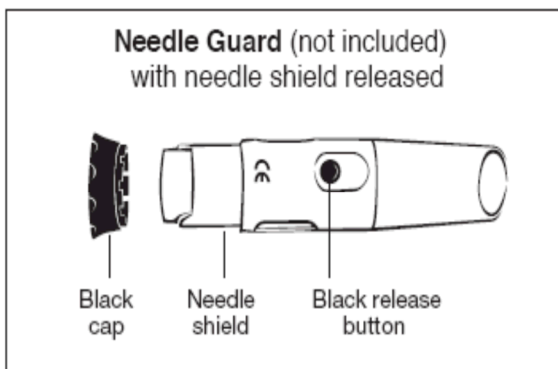
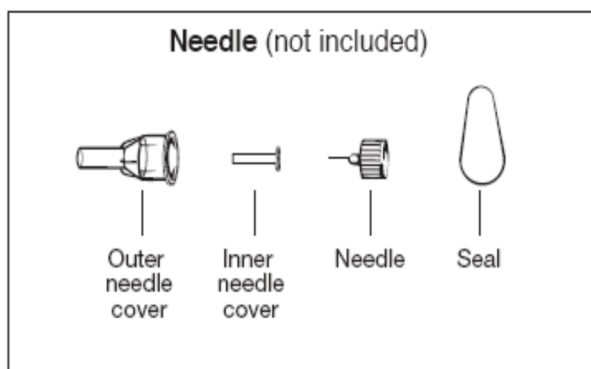
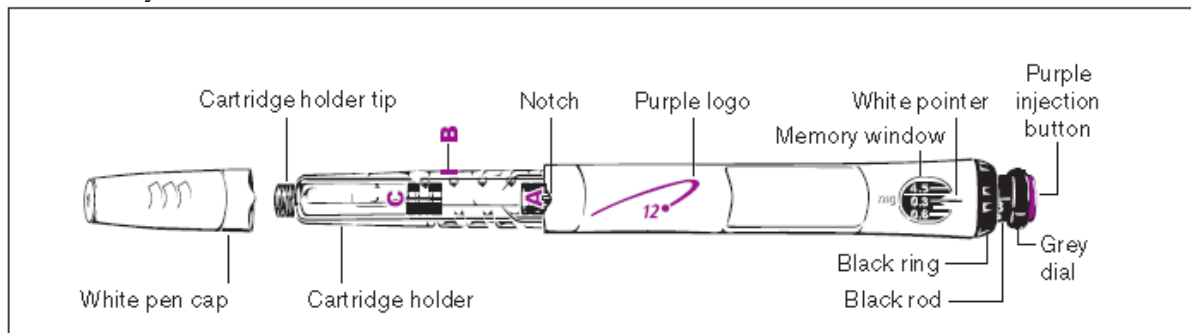
The pen has dose memory. The dose is set once on a new pen. The pen then gives the same dose for each injection. You can use the pen with or without the optional needle guard.

GENOTROPIN[®]

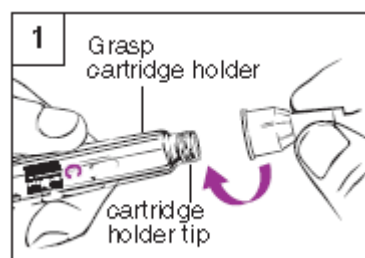
Somatropin (5.3 mg, 12 mg)

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**

- 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.

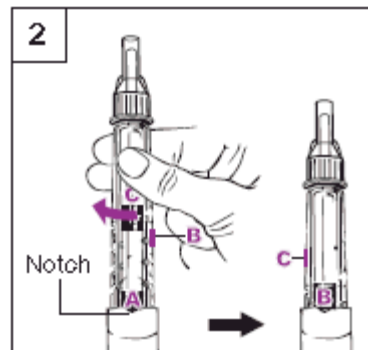


GENOTROPIN[®]

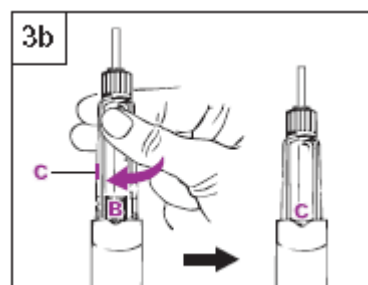
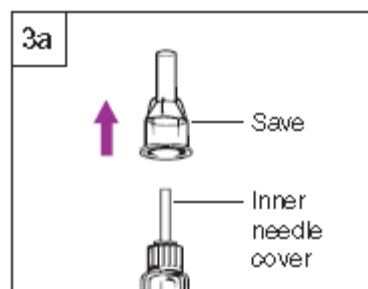
Somatotropin (5.3 mg, 12 mg)

Step 2. Mix the GENOTROPIN

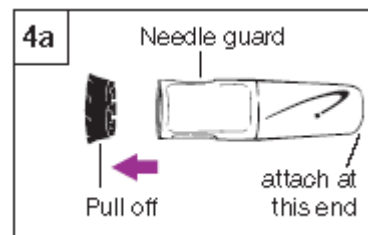
- a. Hold the pen with the needle-end pointing up and the **A** facing you. (Figure 2)
- b. **Firmly** twist the cartridge holder into the pen until **B** clicks into the notch.
 - Gently tilt the pen from side to side. Do not shake the pen. Shaking may damage the growth hormone.
- c. Check that the 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 remove 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)**

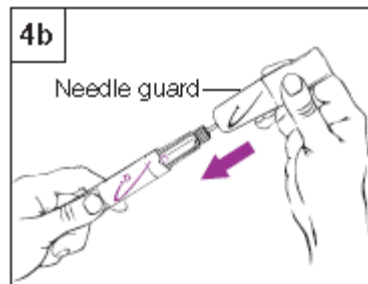
- a. Pull the black cap off the needle guard. (Figure 4a)
 - If the needle shield slides out, push it back into the needle guard until it clicks into place.



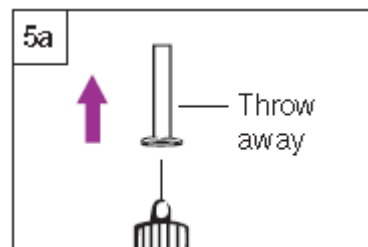
GENOTROPIN[®]

Somatropin (5.3 mg, 12 mg)

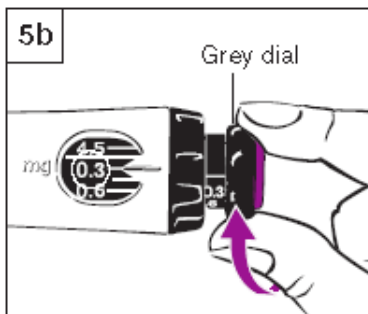
- b. Hold the pen in one hand below the purple logo. With the other hand, hold the needle guard below the needle shield. (Figure 4b)
- c. Line up the black logo on the needle guard with the purple logo on the pen. Carefully push the needle guard onto the pen until it snaps into place.

**Step 5. Prime the Pen**

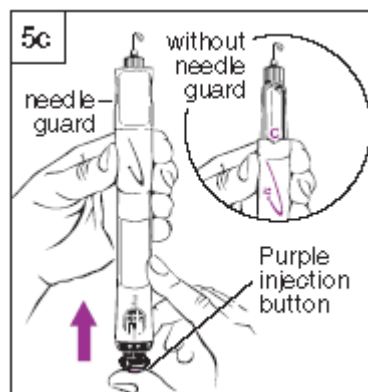
- a. Pull the inner needle cover off. Throw it away. (Figure 5a)



- 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)



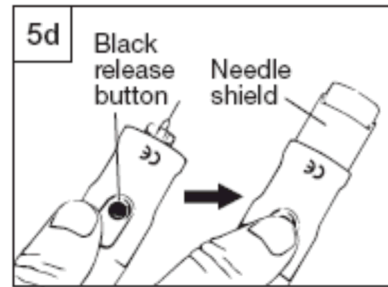
- d. Hold the pen with the needle pointing up. (Figure 5c with and without needle guard)
- e. Push the purple injection button until liquid appears.
- f. If liquid does not appear at Step “e”, repeat Steps b-e in this section up to two more times.
- g. If liquid still does not appear, do not use the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



GENOTROPIN[®]

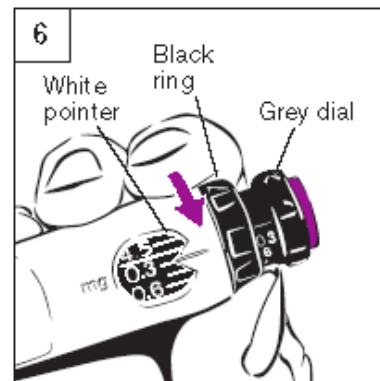
Somatropin (5.3 mg, 12 mg)

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

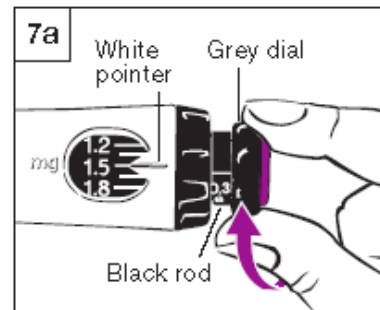
**Step 6. Set the Dose**

- 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.

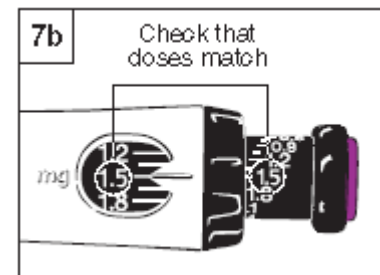
Note: If you cannot turn the black ring, press in the purple injection button until it stops clicking. Then continue to set your dose using the black ring.

**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.

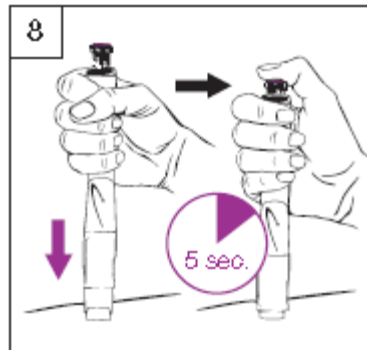


GENOTROPIN[®]

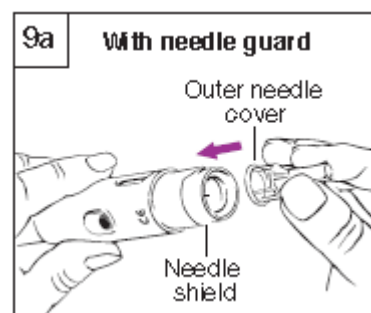
Somatropin (5.3 mg, 12 mg)

Step 8. Give the Injection

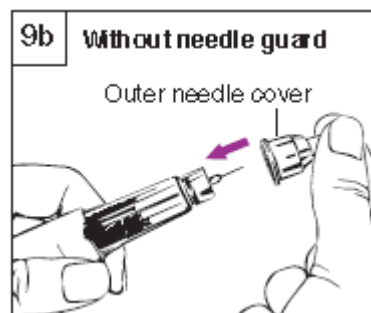
- Prepare an injection site as your doctor or nurse has told you.
- Hold the pen over the injection site.
- Push the pen down to insert the needle into the skin.
- Using your thumb, push the purple injection button down until it stops clicking. (Figure 8)
 - Count for 5 seconds before you pull the needle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

**Step 9. Remove the Needle; Cap and Store Your Pen****Step 9a: With needle guard**

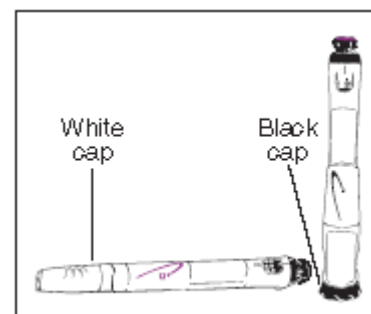
- Place the outer needle cover into the end of the needle shield. (Figure 9a)
- Use the needle cover to push in the needle shield until it locks into place.
- Use the needle cover to unscrew the needle and put it in a proper container for used needles.
- Leave the needle guard on the pen.
- Place the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

**Step 9b: Without needle guard**

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

**Routine Use of GoQuick**

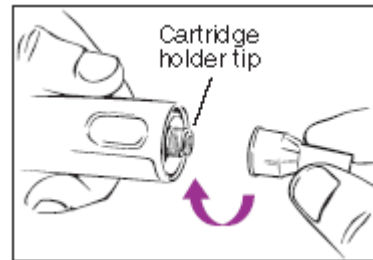
- Pull the black cap from the needle guard or the white cap from the pen.



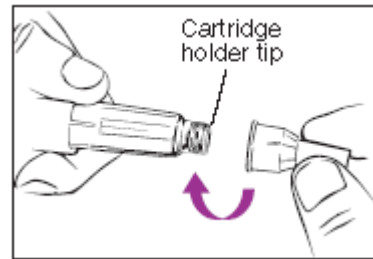
GENOTROPIN[®]

Somatropin (5.3 mg, 12 mg)

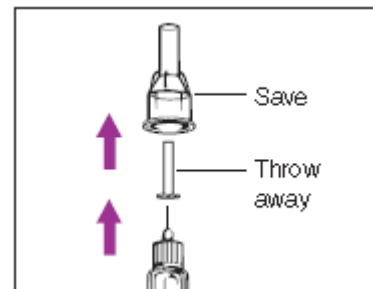
2. Attach a new needle.
 - With the needle guard:
 - If the needle shield releases, push it back into place.
 - Attach a new needle to the cartridge holder tip.



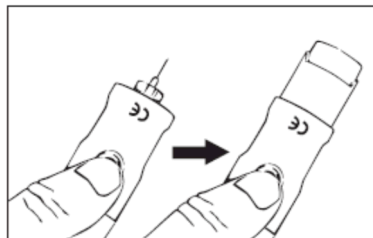
- Without the needle guard:
 - Attach a new needle to the cartridge holder tip.



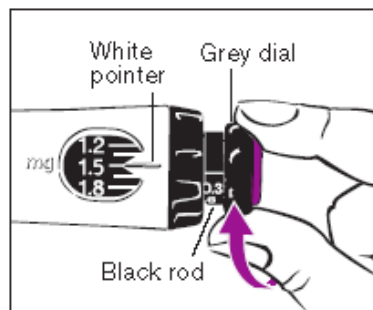
3. Remove both needle covers. Save the outer needle cover to remove the needle.



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



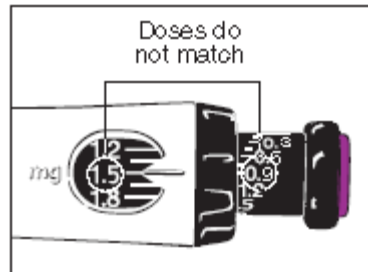
5. To draw up the dose, turn the grey dial until it stops clicking.



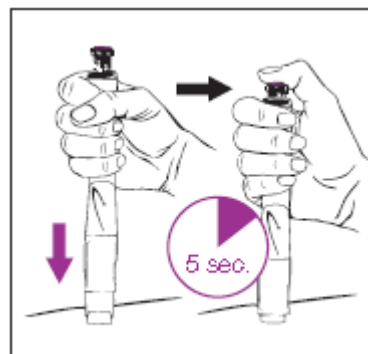
GENOTROPIN[®]

Somatropin (5.3 mg, 12 mg)

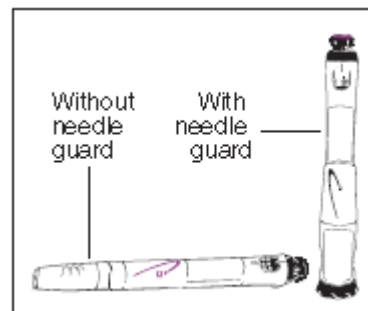
6. Check that the dose you drew up is the same as the dose you set in the memory window.
 - If the dose you drew up is smaller, the pen does not have a full dose of GENOTROPIN.
 - Follow what your doctor or nurse told you to do when the pen does not have a full dose left.



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 cover 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.

GENOTROPIN[®]Somatropin (5.3 mg, 12 mg)

- 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.