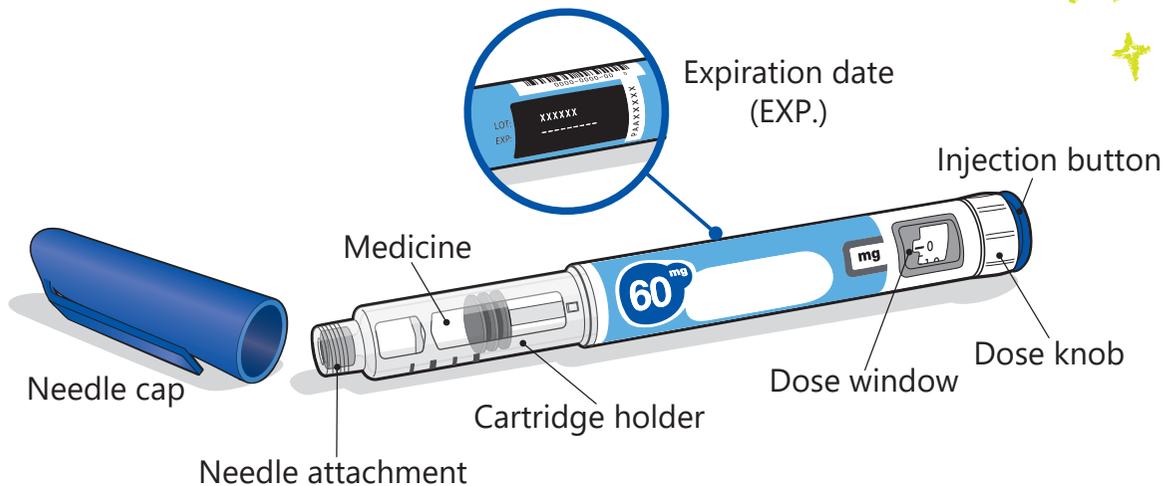


For the treatment of children and adolescents from 3 years of age, with a growth disturbance as a result of insufficient secretion of growth hormone

User Guide for the Ngenla™ Pen (Somatrogen) 24 mg, and 60 mg

Before using Ngenla, **read the patient package insert in its entirety** and receive training by medical staff. If you have further questions, refer to the doctor or pharmacist.




ngenla®
(somatrogen)
injection

SUPPLIES NEEDED BEFORE EACH INJECTION

Included in the carton package:

- 1 Ngenla pen (24 mg, purple colour; or 60 mg, blue colour, in accordance with the doctor's prescription)

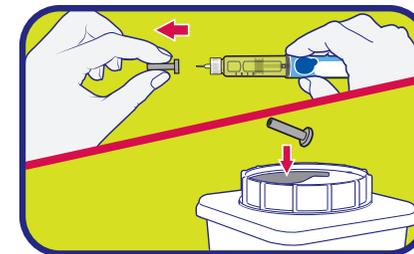
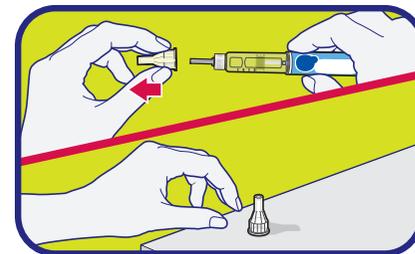
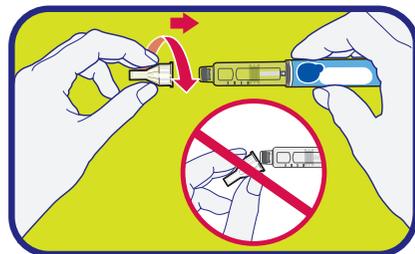
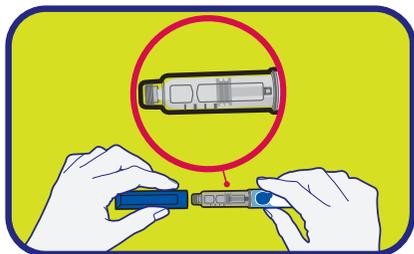
Not included in the carton package:

- 1 new sterile needle for each injection
- Alcohol swabs
- Cotton balls or gauze pads
- Adhesive bandage (band-aid)
- A suitable sharps disposal container for disposal of needles and the pen

Notes:

- Do not shake the pen. Shaking can damage the medicine
- The pen can be used straight from the refrigerator. For a more comfortable injection, leave the pen at room temperature for up to 30 minutes
- **Do not** use the pen if:
 - It has been frozen or exposed to heat (above 32°C) or more than 28 days have passed since first use of the pen
 - If the pen has been removed from the refrigerator for more than 4 hours with each use or if it has been used 5 times
 - If the solution looks cloudy or dark yellow, or if flakes or particles are visible in it
 - It has been dropped
 - It looks broken or damaged
 - If the expiry date has passed

PREPARATIONS FOR INJECTION



Checking the medicine

- Check the name, strength and label on the pen to make sure it is the medicine the doctor prescribed
- Make sure the solution looks clear and colourless to slightly light yellow.
Do not inject the medicine if it looks cloudy or dark yellow, or if it has flakes or particles
- **Note:** It is normal to see one or more bubbles in the medicine

Attaching the needle

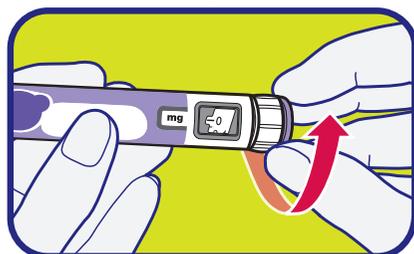
- Take a new needle and pull off the protective paper.
- Gently push and then screw the needle onto the pen
- **Do not** over tighten
- **Note:** Be careful not to attach the needle at an angle. This may cause the pen to leak.

Removing the outer and the inner needle cover

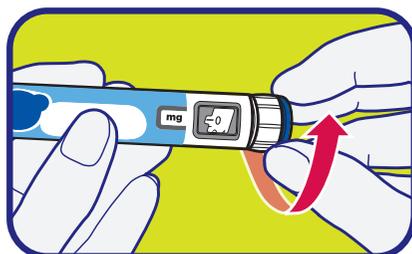
- Pull off the outer needle cover. Keep the outer needle cover. You will need it later to remove the needle.
- **Note:** You should see the inner needle cap after you have removed the outer needle cover. If you do not see it, try to attach the needle again.
- Carefully pull off the inner needle cap to expose the needle
- Throw away the inner needle cap in a sharps container. It is no longer needed

Preparing a new pen (priming) – for first use of a new pen only

A new pen is prepared (primed) before each first use of a new pen. The purpose of setting up the new pen is to remove air bubbles and make sure the correct dose is given.



To prime a 24 mg pen, first turn the dose knob to **0.4 mg**

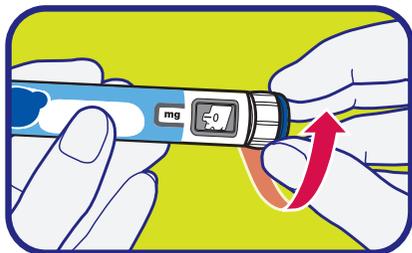


To prime a 60 mg pen, first turn the dose knob to **1.0 mg**

If you turned the dose knob too far, it can be turned back

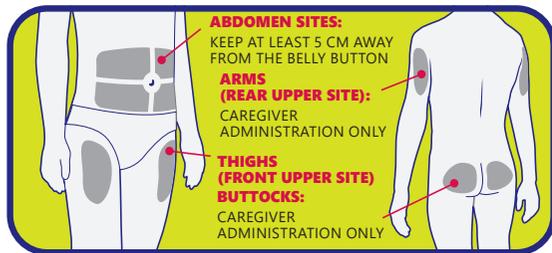
- Hold the pen with the needle pointing up so that the air bubbles can rise. Gently **tap** the 'Cartridge holder' so that the air bubbles float toward the top.
Important: Perform this step even if you do not see air bubbles
- **Press the 'injection button'** until it cannot go any further and "0" appears in the dose window.
Check for liquid at the needle tip. If liquid appears, the pen is set up.
- If liquid still hasn't appeared after you have repeated these steps five (5) times, attach a new needle and try one (1) more time. **Do not** use the pen if a drop of liquid still does not appear. Inform the doctor, nurse or pharmacist, and use a new pen.

SETTING THE PRESCRIBED DOSE AND INJECTING THE DOSE



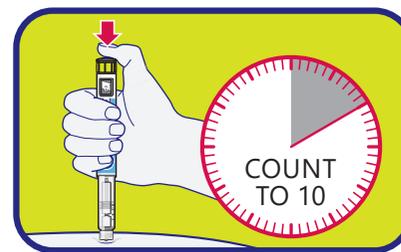
Turn the 'dose knob' to set the required dose

- In a 24 mg pen, the dose knob turns 0.2 mg at a time
- In a 60 mg pen, the dose knob turns 0.5 mg at a time
- The dose can be increased or decreased by turning the 'dose knob' in either direction
- **Important: Do not** press the 'injection button' while setting the dose
- **If there is not enough medicine left in the pen for the full dose, you can either:**
 - inject the amount left in the pen, and then prepare a new pen to complete the dose in full. Remember to subtract the dose that was already injected
 - or take a new pen and inject the full dose



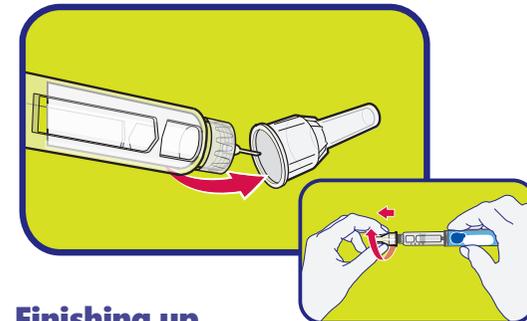
Choosing and disinfecting the injection site

- Choose the most suitable place in the body to inject, as recommended by the doctor, nurse, or pharmacist
- If more than one injection is needed to complete the full dose, each injection should be given in a different site on the body
- Clean the injection site with an alcohol swab. Allow the injection site to dry. **Do not** touch the injection site after cleaning
- **Do not** inject into bony areas, areas that are bruised, red, sore, hard, or areas that have scars or skin conditions



Injecting the dose

- Hold the pen so you can see the numbers in the dose window.
- Insert the needle straight into the skin. Keep holding the needle in the same position in the skin. **Press the 'injection button'** until it cannot go any further and "0" appears in the dose window
- **Continue pressing the 'injection button' while counting to 10.** Counting to 10 will allow injection of the full dose of medicine
- After counting to 10, release the injection button and slowly remove the pen from the injection site by pulling the needle **straight out**
- **Note:** There may be a drop of medicine at the needle tip. This is normal and does not affect the dose that was injected



Finishing up

- Carefully place the outer needle cover back on the needle
- Unscrew the capped needle from the pen. Gently pull until the capped needle comes off
- Dispose of your used pen needles in a sharps container appropriate for used needles
- Replace the pen cap on the pen. **Do not** recap the pen with a needle attached to it
- Press lightly on the injection site with a clean cotton ball or gauze pad, and hold for a few seconds. The injection site can be covered with a small adhesive bandage (band-aid), if needed
- If the pen is empty or if **more than 28 days** have passed since the first use, throw it away even if it still contains medicine residue. Throw the pen away in a sharps container

Storage:

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Do not use the pre-filled pen if more than 28 days have passed from the first use

Before first use of Ngenla:

- Store in a refrigerator (2°C-8°C).
- Do not freeze
- Store Ngenla in the outer carton package in order to protect from light
- Remove Ngenla from the refrigerator prior to use. Ngenla may be held at room temperature for up to 4 hours (up to 32°C).
- Do not use the medicine if the solution looks cloudy or dark yellow. Do not use the medicine if flakes or particles are visible in it.
- Do not shake the pen. Shaking can damage the medicine

After first use of Ngenla:

- Use within 28 days after first use. Store in a refrigerator (2°C-8°C). Do not freeze.
- Store Ngenla with the pen cap on in order to protect from light
- Do not store the pre-filled pen with a needle attached
- Discard the pen after the last dose, even if it contains medicine residue
- Ngenla may be held at room temperature (up to 32°C) for up to 4 hours with each injection, for a maximum of 5 times. Return Ngenla to the refrigerator after each use.
- Do not leave the pen at room temperature for more than 4 hours with each use.
- If it has been more than 28 days since first use of the pen, dispose of it, even if it contains medicine residue. If your or your child's pen has been exposed to temperatures higher than 32°C, or has been removed from the refrigerator for more than 4 hours with each use or if it has been used 5 times, dispose of it even if it still contains medicine residue.

To help remember when to dispose of the pen, the date of first use can be recorded on the pen label.

A small amount of medicine may remain in the pen after all the doses have been administered correctly. Do not try to use the remaining medicine. After the last dose has been given, throw the pen away.

Do not dispose of the medicine via household waste. If necessary, ask the pharmacist how to throw away medicines in order to protect the environment.



Before the first use of the Ngenla pen, you must receive training by medical staff on how to inject the medicine.

Pfizer provides Ngenla patients with training and support services for the injection pens, provided by a devoted, professional team of nurses. The service is not mandatory.



To coordinate a training session, or to receive telephone support, contact **the Nurse Call Centre at telephone number: 09-9700555**

For more information about the medicine, read the patient package insert:



Patient
Package Insert
Ngenla 24 mg



Patient
Package Insert
Ngenla 60 mg

For further questions, as needed, contact your attending physician or pharmacist. The information is correct as of September 2024

To report side effects:
ISR.AEReporting@pfizer.com

To report quality complaints:
israelProdComplaints@pfizer.com

To report side effects to the Ministry of Health:
<https://sideeffects.health.gov.il>