PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Ngenla® 24 mg

Solution for subcutaneous injection

Ngenla® 24 mg pre-filled pen contains:
Somatrogon 24 mg/1.2 ml in cartridge
(Somatrogon 20 mg/1 ml)

For the list of inactive and allergenic ingredients, see section 6 "Further Information" and section 2 "Important information about some of the ingredients of the medicine".
Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

WHAT SHOULD I KNOW ABOUT NGENLA?

1. WHAT IS THE MEDICINE INTENDED FOR?

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.

Therapeutic group:
Hypothalamus and pituitary gland hormones and their analogues, growth hormone (somatropin and somatropin agonists).

Ngenla contains the active substance somatrogon, a form of growth hormone generated using 'recombinant DNA' technology (a substance generated in cells grown in a laboratory). Natural human growth hormone is needed for bones and muscles to grow in the body. It also helps fat and muscle tissues to develop in the right amounts. Ngenla is used to treat children and adolescents from 3 years of age who do not have enough growth hormone and who are not growing at a normal rate.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you or your child is hypersensitive (allergic) to the active ingredient, somatrogon (see section "Special warnings regarding use of the medicine"), or to any of the additional ingredients contained in the medicine (see section 6).
- you or your child has an active tumor (cancer). Consult the doctor if you or your child has or has had an active tumor. The tumor must be inactive, and you or your child must have finished the anti-tumor treatment before starting treatment with Ngenla.

- you or your child stopped growing because of closure of the growth plates (closed epiphyses), meaning that you have been told by the doctor that the bones have stopped growing.
- you or your child has a serious illness (for example, complications following open heart surgery, abdominal surgery, acute respiratory failure, multiple accidental trauma or similar conditions).
- you or your child is about to have, or have had, a major operation, or to be hospitalized for any reason, tell the attending doctor and all other doctors that you/he is being treated with growth hormone (see section “Special warnings regarding use of the medicine”).

Special warnings regarding use of the medicine

During and before treatment with Ngenla, tell the doctor if any of the following apply to you:

- You or your child are developing a serious allergic reaction (hypersensitivity), stop using the medicine and consult the attending doctor immediately. Sometimes serious allergic reactions such as hypersensitivity, including anaphylaxis or angioedema (difficulties breathing or swallowing, or swelling of the face, lips, throat or tongue) have occurred. If you or your child has any of the following symptoms of a serious allergic reaction including:
  - breathing problems
  - swelling of the face, mouth, or tongue
  - urticaria (hives, lumps rising under the skin)
  - rash
  - fever
- You or your child is receiving replacement corticosteroid therapy (with glucocorticoids), consult the doctor regularly as there may be a need to adjust the dosage of your glucocorticoid medicines.
- You or your child has Prader-Willi syndrome, do not use Ngenla unless you also have growth hormone deficiency.
- You or your child is being treated with insulin or other diabetes medicines, the doctor may need to adjust the insulin dosage. Do not use Ngenla if you or your child has diabetes and associated severe/worsening of eye disease.
- You or your child had any type of tumor (cancer).
- You or your child experiences changes in vision, severe or frequent headaches, associated with nausea, vomiting, or experience lack of control of voluntary muscles or coordination of voluntary movements, such as walking or picking up objects, difficulty with speech, eye movement or swallowing, especially at the start of treatment, tell the doctor immediately. These may be signs of a temporary increase in pressure within the brain (intracranial hypertension).
- You or your child is seriously ill (for example, complications following open heart surgery, abdominal surgery, acute respiratory failure, multiple accidental trauma or similar conditions). If you or your child is about to have, or have had, a significant

medical procedure, or to be hospitalized for any reason, inform the attending doctor and all other doctors that you/he is being treated with growth hormone (see section "Do not use the medicine if").
- You or your child develops a severe stomach ache during the course of treatment with Ngenla, as this may be a symptom of inflammation of the pancreas.
- You or your child notices a sideways curvature in your spine (scoliosis), you or him will need to be checked often by the doctor.
- While growing, you or your child develops a limp or hip or knee pain, consult the doctor immediately. These may be symptoms of bone disorders in the hip bones, which may happen during periods of rapid growth.
- You or your child is taking or stops taking oral contraception or estrogen-containing hormonal replacement therapy, the doctor may recommend adjusting the dose of Ngenla.

Children and adolescents

Ngenla is not intended for children under 3 years of age. Information on the treatment for this age group is not available. Efficacy and safety of the treatment in this age group has not been tested.

Tests and follow-up

- The doctor will check your or your child's thyroid gland function at intervals and, if necessary, will prescribe treatment or adjust the dosage of existing treatment so that Ngenla can work properly.
- The doctor will monitor for high sugar levels (hyperglycemia) in your or your child's blood, during treatment with Ngenla.

Drug interactions

If you are taking or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist, especially if you or your child is taking:
- Corticosteroids (glucocorticoids) as replacement therapy - these medicines may reduce the effect of Ngenla on growth. Consult the doctor regularly, as there may be a need to adjust the glucocorticoid dosage.
- Insulin or other diabetes medicines - consult the doctor as the dosage may have to be adjusted.
- Thyroid hormones - consult the doctor as the dosage may have to be adjusted.
- Estrogen taken orally - consult the doctor as the Ngenla dosage may have to be adjusted.
- Ciclosporin (a medicine that weakens the immune system after transplantation) - consult the doctor as the dosage may have to be adjusted.
- Medicines to treat epilepsy (anticonvulsants) - consult the doctor as the dosage may have to be adjusted.

Pregnancy and breastfeeding

If the patient is pregnant, breastfeeding, or think she may be pregnant or is trying to conceive, refer to a doctor for advice before using this medicine.

Ngenla has not been tested in pregnant women and it is not known if this medicine can harm an unborn baby. It is therefore recommended to avoid using Ngenla during pregnancy. If there is a chance of becoming pregnant, do not use Ngenla unless a reliable contraception is also being used.

It is not known whether the medicine can pass into breast milk. If you plan to breastfeed, consult the doctor. The doctor will help decide if it is necessary to stop breastfeeding, or to stop taking Ngenla, considering the benefits of breastfeeding for the baby and the benefits of Ngenla.

Driving and using machinery

Ngenla does not affect or has negligible effect on the ability to drive and use machinery.

Important information about some of the ingredients of the medicine

Ngenla contains less than 1 mmol sodium (23 mg) per dose and is therefore considered “sodium-free”.

Ngenla contains a preservative called metacresol. In very rare cases, the presence of metacresol can cause inflammation (swelling) in the muscles. If you or your child experiences muscle pain or pain at the injection site, inform the doctor.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor’s instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the doctor only. Only a specialist doctor with experience in growth hormone treatment, who has diagnosed you or your child can decide on commencement of treatment with this medicine.

- The appropriate dosage is calculated by the doctor based on the patient’s body weight in kg. The recommended dosage is usually 0.66 mg per kg body weight, once weekly. Do not change the dosage unless instructed to do so by the doctor.
- If you or your child was treated with a daily growth hormone, the doctor will instruct you to wait with the use of Ngenla untill the day after the last injection of the daily growth hormone and then to continue with Ngenla once a week.
- Ngenla is available as a multi-dose pre-filled pen in 2 different strengths (Ngenla 24 mg or Ngenla 60 mg).
  The doctor will determine the type of pen based on the dosage recommended for you or your child (see section 6).
- Before first use of the pen, you or your child must receive training by a nurse or doctor on how to inject the medicine. The medicine is intended to be injected under the skin (subcutaneous injection) using a pre-filled pen. Do not inject into a vein or muscle.

- The recommended places for injection of the medicine are the abdomen, thigh, buttocks or upper part of the arm. Injection into the buttocks or the upper part of the arm must be done by a caregiver (health care provider or other caregiver).
- Alternate the injection site on the body with each injection.
- If more than one injection is necessary to deliver the required dose, each injection should be administered in a different area of the body.

When to use the medicine:
- The medicine is given once a week. Inject the medicine on the same day each week.
- Record which day of the week you used Ngenla so that you can remember to inject on the same day once a week.
- If necessary, the injection day can be changed as long as it has been at least 3 days since the last injection was given. After selecting the new day, continue injecting the medicine on that day each week.

Complete the treatment regimen as recommended by the doctor.
See section “Instructions for use Ngenla 24 mg” for detailed instructions for use.
Do not exceed the recommended dosage.

If you accidentally used a higher dosage
If you used an overdose or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you. The doctor may have to check your or your child’s blood sugar level.

If you forget to inject the medicine
If you forgot to inject this medicine at the scheduled time:
- If 3 days or less have passed since the day you should have injected Ngenla, inject as soon as you remember. The following injection should be given on the next scheduled injection day.
- If more than 3 days have passed since the day you should have injected Ngenla, skip the missed dose and receive the following injection on the next scheduled day. A regular injection day should be maintained.
- Do not use a double dose to make up for a forgotten dose.

Adhere to the treatment regimen as recommended by the doctor.
Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor or pharmacist. Discontinuing the medicine reduces the effectiveness of the treatment.

Do not take medicines in the dark! Check the label and the dose <u>each time</u> you take medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Ngenla may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Refer to a doctor as soon as possible if the following side effects occur (see section 2 "Special warnings regarding use of the medicine"):

- allergic reaction (hypersensitivity)
- inflammation of the pancreas (which causes symptoms of abdominal pain, nausea, vomiting or diarrhea)
- increased intracranial pressure (which causes symptoms such as severe headache, vision disturbances or vomiting)
- lateral curvature of the spine
- limping or pain in the thigh or knee

Very common side effects (may occur in more than 1 in 10 patients):

- Headache
- Bleeding, inflammation, itching, pain, redness, soreness, stinging, tenderness or warmth at the injection site (injection site reactions)
- Fever (pyrexia)

Common side effects (may occur in up to 1 in 10 patients):

- Decrease in the number of red blood cells in the blood (anemia)
- Increase in the number of eosinophils in the blood (eosinophilia)
- Decrease in the blood level of the thyroid hormone (hypothyroidism, underactive thyroid gland)
- Allergic inflammation of the conjunctiva, the outer layer of the eye (allergic conjunctivitis)
- Joint pain (arthralgia)
- Pain in hands or legs

Uncommon side effects (may occur in up to 1 in 100 patients):

- The adrenal glands do not make enough steroid hormones (adrenal insufficiency)
- Rash

Other side effects not seen with Ngenla but which have been reported in other growth hormone preparations, may include:

- Tissue growth (noncancerous or cancerous)
- Type 2 diabetes
- Increased intracranial pressure (which causes symptoms such as strong headache, visual disturbances or vomiting)
- Numbness or tingling
- Joint or muscle pain
- Breast enlargement in boys and men
- Skin rash, reddening and itching
- Water retention (which shows as puffy fingers or swollen ankles)
- Facial swelling
- Pancreatitis (which causes symptoms of stomach pain, nausea, vomiting or diarrhea)

In very rare cases, the presence of metacresol can cause inflammation (swelling) in muscles. If you or your child experiences muscle pain or pain at the injection site, inform the doctor.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not listed in this leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

- 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.
- Do not store the pen in a place where the temperature exceeds 32°C.
- 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.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:
Sodium Chloride, m-Cresol, Trisodium Citrate Dihydrate, Poloxamer 188, L-Histidine, Citric Acid Monohydrate, Water for Injection.

What the medicine looks like and the contents of the package:
Each package contains Ngenla® 24 mg solution for injection in a single pre-filled pen. Ngenla® is a clear and colorless to light yellow solution for injection in a pre-filled pen. The 'dose button', label and pen cap are colored lilac.
Each pre-filled pen contains 24 mg somatrogon in 1.2 mL solution. Each pre-filled pen delivers doses ranging from 0.2 mg up to 12 mg per injection, in 0.2 mg increments. 1 ml solution contains 20 mg of the active ingredient, somatrogon.
License Holder and Address: Pfizer Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach 46725.
Registration number of the medicine in the National Drug Registry of the Ministry of Health: 175-09-37406
Approved in 01/2024 in accordance with the Ministry of Health guidelines.

Instructions for use Ngenla 24 mg

Important information about the Ngenla pen

- Ngenla 24 mg for injection is a multi-dose pre-filled pen containing 24 mg somatrogon.
- The patient himself, a caregiver, doctor or nurse can inject Ngenla. **Do not** try to inject Ngenla yourself before undergoing training on how to correctly inject and have read and understood the Instructions for Use. If the doctor or nurse decides that you or a caregiver can inject Ngenla at home, you must receive training on the right way to prepare and inject Ngenla. It is very important that you read, understand, and follow these instructions so that you will be able to inject Ngenla the right way. It is important to consult with the doctor, nurse or pharmacist to be sure you understand the dosage instructions that have been determined.
- To remember when to inject Ngenla, you can mark the regular injection day on your calendar ahead of time. Consult the doctor, nurse or pharmacist if you have questions about the right way to inject Ngenla.
- Each turn (click) of the 'dose knob' increases the dose by 0.2 mg of medicine. You can give from 0.2 mg to 12 mg in a single injection. If the dose is more than 12 mg, more than one injection should be administered.

- A small amount of the medicine may remain in the pen after all doses have been correctly given. This is normal. Do not try to use the remaining solution, rather, get rid of the pen in the correct way.
- **Do not share** the pen with others, even if the needle has been changed. You may cause serious infection to others by doing so, or get a serious infection.
- Always use a new sterile needle for each injection. This will reduce the risk of contamination, infection leakage of the medicine, and blocked needles leading to the wrong dose.
- **Do not shake** the pen. Shaking can damage the medicine.
- The pen **is not recommended** for use by the blind or visually impaired without the assistance of a person trained in the proper use of the medicine.

Supplies needed before each injection:

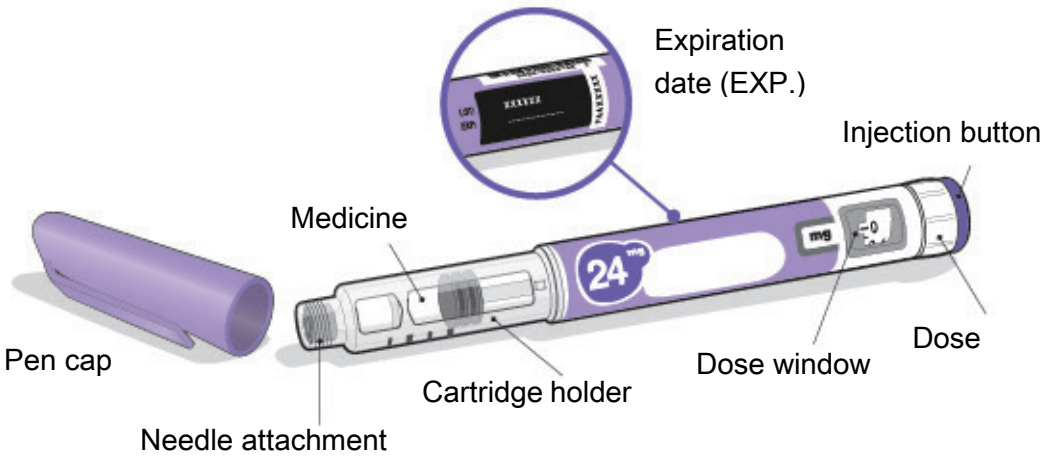
Included in the carton package:

- 1 Ngenla 24 mg pen.

Not included in the carton package:

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

Ngenla 24 mg pen:

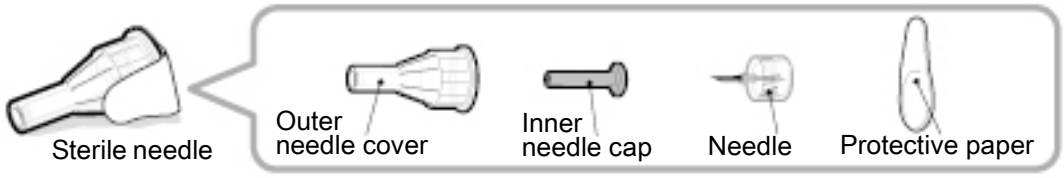


Needles to use:

Pen needles **are not included** in the Ngenla package. Pen needles from 4 mm to 8 mm can be used.

- Needles to use with your Ngenla pen:
  - 31G or 32G.
- Consult the doctor, nurse or pharmacist about the right needle for you.

Sterile needle (example) not included in the package:



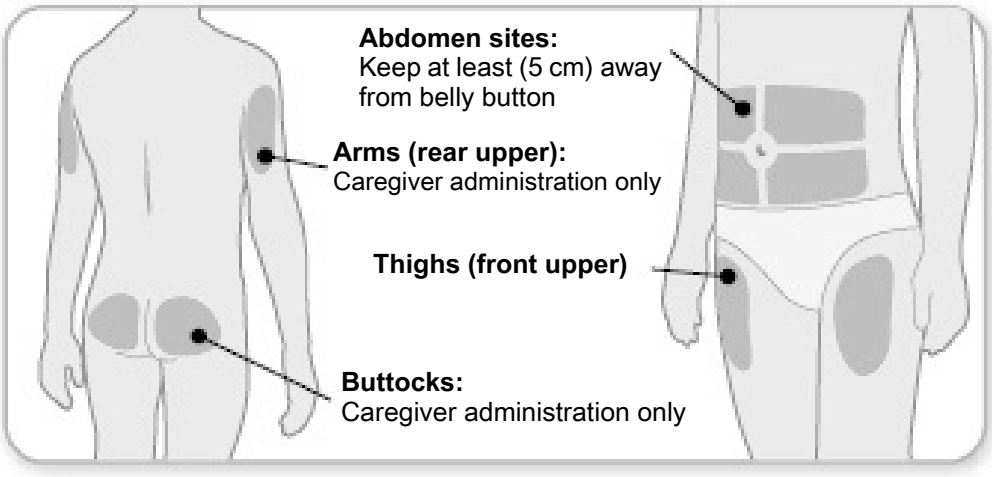
Caution: Never use a bent or damaged needle. Always handle pen needles with care to make sure you do not prick yourself (or anyone else) with the needle. **Do not** attach a new needle to the pen before you are ready for the injection.

Preparations for injection

Step 1. Getting ready

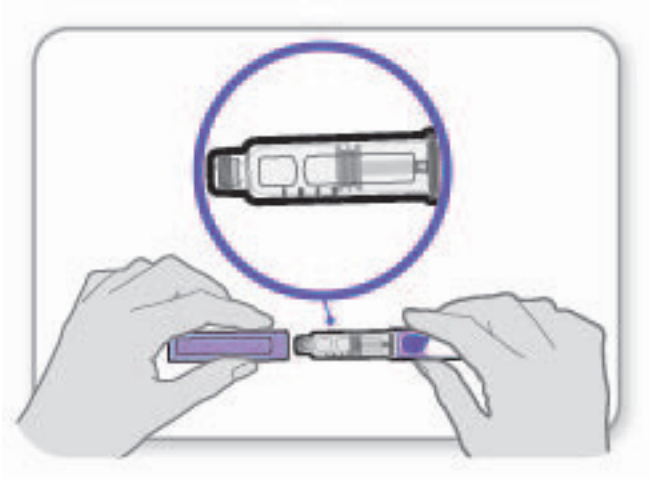
- Wash and dry your hands.
- The pen can be used straight from the refrigerator. For a more comfortable injection, leave the pen at room temperature for up to 30 minutes **(see section 5 "How should the medicine be stored?")**.
- Check the name, strength, and label of the pen to make sure it is the medicine the doctor prescribed.
- Check the expiry date on the pen label. **Do not** use if the expiry date has passed.
- **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 the first use of the pen **(see section 5 "How should the medicine be stored?")**.
  - it has been dropped.
  - it looks broken or damaged.
- **Do not** remove the pen cap from the pen - until you are ready to inject.

Step 2. Choosing and disinfecting the injection site



- Ngenla can be injected into the abdomen (belly), thighs, buttocks, or upper part of the arms.
- 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.
- **Do not** inject into bony areas, areas that are bruised, red, sore, hard, or areas that have scars or skin conditions.
- Clean the injection site with an alcohol swab.
- Allow the injection site to dry.
- **Do not** touch the injection site after cleaning.

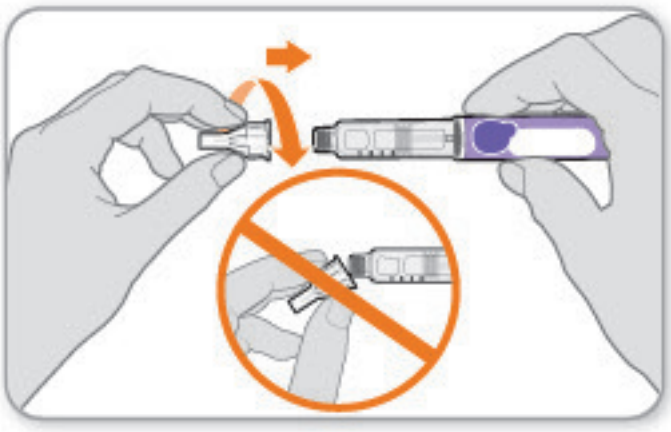
Step 3. Check the medicine



- Pull off the pen cap and keep it for after the injection.
- Check the medicine inside the ‘cartridge holder’.
- Make sure the solution looks clear and colorless to slightly light yellow. **Do not** inject the medicine if it looks cloudy or dark yellow.
- Make sure the medicine is free of flakes or particles. **Do not** inject the medicine if it has flakes or particles.

Note: It is normal to see one or more bubbles in the medicine.

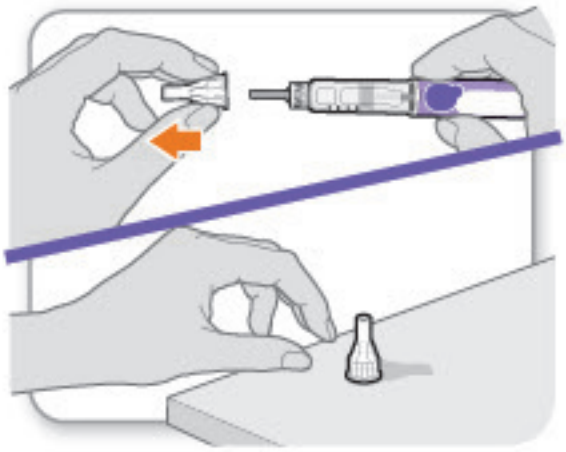
Step 4. Attaching the needle



- Take a new needle and pull off the protective paper.
- Line the needle up with the pen keeping them both straight.
- 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.
Caution: Needles have sharp tips at both ends. Exercise caution to avoid pricking yourself (or anyone else) with the needle.

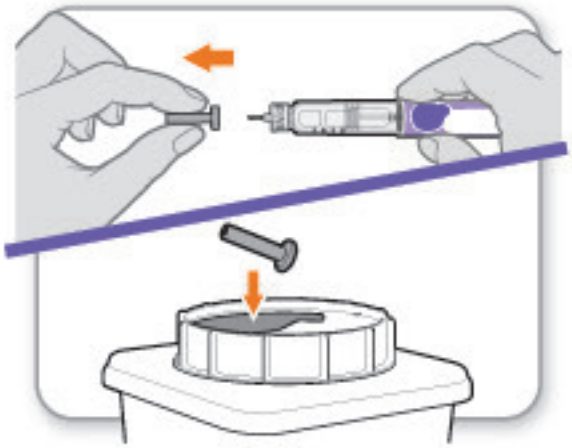
Step 5. Removing the outer needle cover



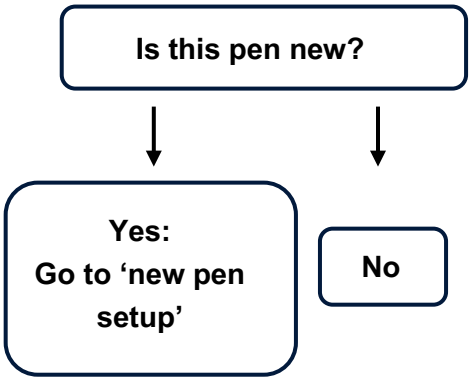
- Pull off the outer needle cover.
- Keep the outer needle cover. You will need it later to remove the needle.

Note: You should see an inner needle cap after you have removed the outer needle cover. If you do not see it, try to attach the needle again.

Step 6. Removing the inner needle cap



- Carefully pull off the inner needle cap to show the needle.
- Throw away the inner needle cap in a sharps container. It is no longer needed.



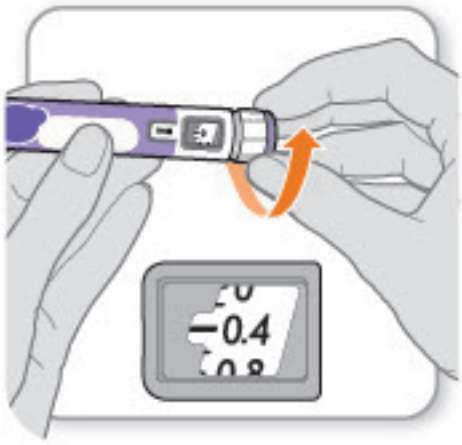
Preparing a new pen (priming) – for first use of a new pen only

You must set up each new pen (priming) before using it for the first time

- A new pen is prepared 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.

Important: Skip Steps A-C if you have already prepared the pen.

Step A Set knob to 0.4



- Turn the dose knob to **0.4**.

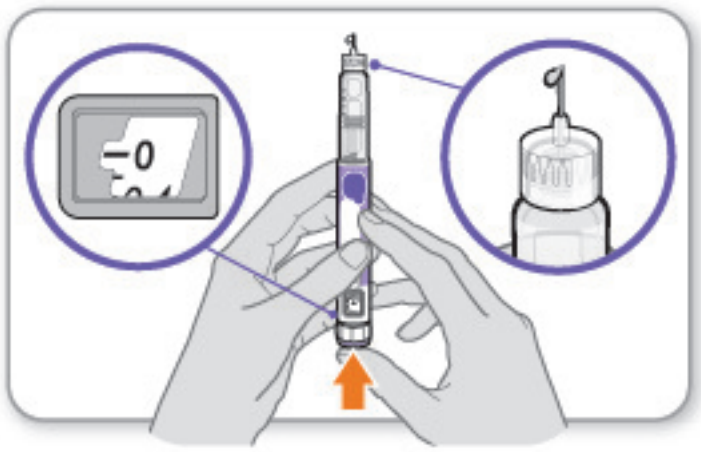
Note: If you turned the dose knob too far, it can be turned back.

Step B Tap the 'cartridge holder'

- 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 Step B even if you do not see air bubbles.

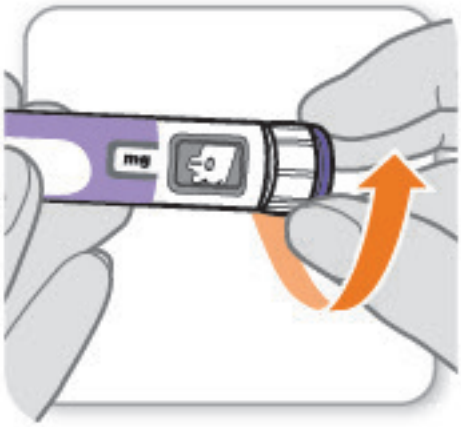
Step C Press the ‘injection button’ and check for liquid



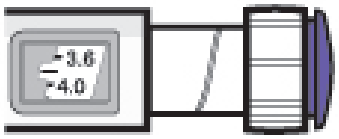
- **Press the ‘injection button’** until it cannot go any further and **“0”** appears in the dose window.
- **Check** for liquid at the needle tip. If liquid appears, the pen is set up.
- Always make sure that a drop of liquid appears before the injection. If liquid does not appear, repeat Steps A-C.
  - If liquid still hasn’t appeared after you have repeated Steps A-C 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

Step 7. Set the dose

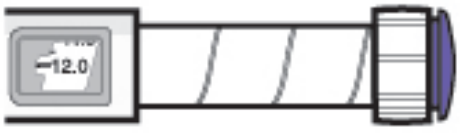


Example A:



3.8 mg shown in the dose window

Example B:



12.0 mg shown in the dose window

- Turn the ‘dose knob’ to set the required dose.
  - The dose can be increased or decreased by turning the ‘dose knob’ in either direction.

- The dose knob turns 0.2 mg at a time.
- The pen contains 24 mg of medicine but only a dose of up to 12 mg can be set for a single injection.
- The dose window shows the dose in mg. **See Examples A and B.**

- **Always check the dose window to make sure that the correct dose was set. Important: Do not** press the 'injection button' while setting the dose.

What should I do if I cannot set the dose I need?

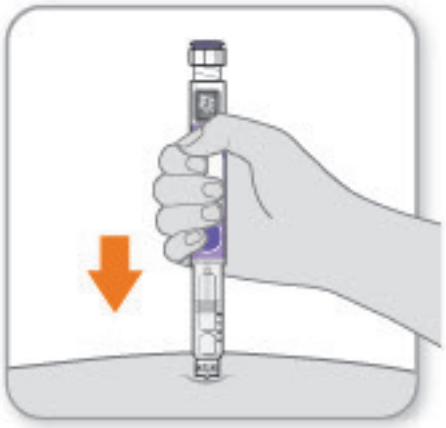
- If the dose the doctor prescribed is more than 12 mg, more than one injection will be needed.
- Between 0.2 mg and 12 mg can be injected in a single injection.
  - If you need help dividing up the dose the right way, consult the doctor, nurse or pharmacist.
  - Use a new needle for each injection **(See Step 4: 'Attaching the needle')**.
  - If normally 2 injections must be given to receive the full prescribed dose, be sure the second injection is given.

What should I do if I do not have enough medicine left in my pen?

- If the pen contains less than 12 mg of medicine, the 'dose knob' will stop with the remaining amount of medicine shown in the 'dose window'.
- If there is not enough medicine left in the pen for the full dose, either to:
  - 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. For example, if the dose is 3.8 mg and the dose knob can only be set to 1.8 mg, inject another 2.0 mg with a new pen.
  - or take a new pen and inject the full dose.

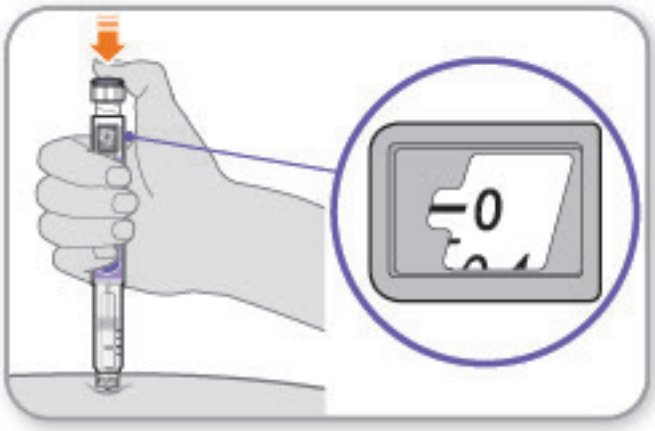
Injecting the dose

Step 8. Inserting the needle



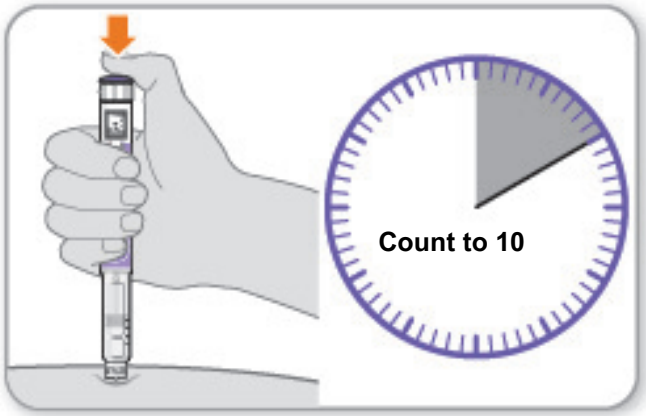
- Hold the pen so you can see the numbers in the dose window.
- Insert the needle straight into the skin.

Step 9. Injecting the medicine



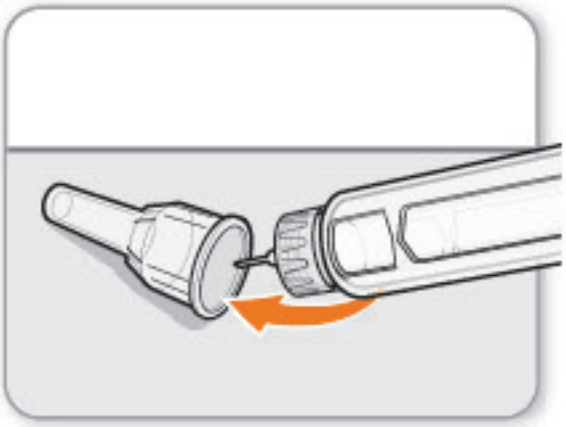
- Keep holding the needle in the same position in the skin.
- **Press the 'injection button'** until it cannot go any further and **"0"** appears in the dose window.

Step 10. Counting to 10



- **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.

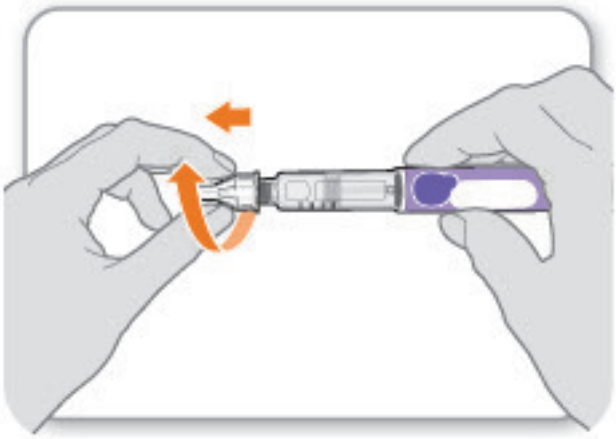
Step 11. Attaching the outer needle cover



- Carefully place the outer needle cover back on the needle.
- Press on the outer needle cover until it is secure.

Caution: Never try to put the inner needle cap back on the needle. This can cause needle pricks.

Step 12. Removing the needle

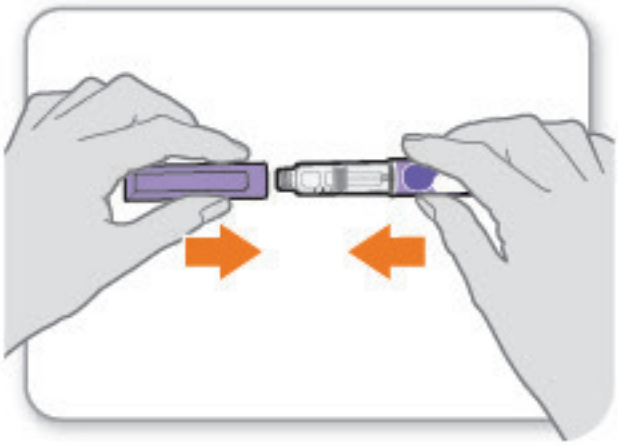


- Unscrew the capped needle from the pen.
- Gently pull until the capped needle comes off.

Note: If the needle is still attached, replace the outer needle cover and try again. Be sure to apply pressure while unscrewing the needle.

Dispose of your used pen needles in a sharps container appropriate for used needles, in accordance with the Doctors', pharmacists' or nurses' instructions and the health and environmental guidelines. Keep this container out of the reach of children. **Do not** reuse needles.

Step 13. Replacing the pen cap



- Replace the pen cap on the pen.
- Do not recap the pen with a needle attached to it.

If there is medicine left in the pen, store in the refrigerator between injections **(See section 5 "How should the medicine be stored?).**

Step 14. After the injection

- Press lightly on the injection site with a clean cotton ball or gauze pad, and hold for a few seconds.
- **Do not** rub the injection site. You may have slight bleeding. This is normal.
- The injection site can be covered with a small adhesive bandage, 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. Throw the pen away in a sharps container.
- In order to remember when to throw away the pen, it can help to record the date of first use on the label of the pen and below:
  Date of first use _____ / _____ / _____