Package leaflet: Information for the patient

Ngenla 24 mg solution for injection in pre-filled pen

somatrogon

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you or the child in your care only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours or those of the child in your care.
- If you or the child in your care get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ngenla is and what it is used for

Ngenla contains the active substance somatrogon, a modified form of human growth hormone. Natural human growth hormone is needed for bones and muscles to grow. It also helps your 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 are not growing at the normal rate.

The active substance in Ngenla is made by 'recombinant DNA technology.' This means that it is grown in cells that have been modified in the laboratory so that they can produce it.

2. What you need to know before you use Ngenla

Do not use Ngenla
- If you or the child in your care are allergic to somatrogon (see Warnings and precautions) or any of the other ingredients of this medicine (listed in section 6).
- If you or the child in your care have an active tumour (cancer). Tell your doctor if you or the child in your care have or have had an active tumour. Tumours must be inactive, and you or the child in your care must have finished your anti-tumour treatment before starting treatment with Ngenla.
- If you or the child in your care have stopped growing because of closure of the growth plates (closed epiphyses) meaning that you or the child in your care have been told by your doctor that your bones have stopped growing.
- If you or the child in your care are seriously ill (for example, complications following open heart surgery, abdominal surgery, acute respiratory failure, multiple accidental trauma or similar

conditions). If you or the child in your care 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.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Ngenla:

- If you or the child in your care develop a serious allergic reaction, stop using Ngenla, talk to your doctor right away. 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 the child in your care have any of the following symptoms of a serious allergic reaction:
    - breathing problems
    - swelling of your face, mouth, and tongue
    - hives (nettle rash, lumps rising under the skin)
    - rash
    - fever
- If you or the child in your care have replacement therapy with corticosteroid medicines (glucocorticoids) you or the child in your care should consult your doctor regularly as you or the child in your care may need adjustment of your glucocorticoid dose.
- Your doctor should check at intervals how well the thyroid gland is working in you or the child in your care and if necessary may prescribe treatment or adjust the dose of existing treatment as this may be needed for Ngenla to work properly.
- If you or the child in your care have Prader-Willi syndrome, you or the child should not be treated with Ngenla unless you or the child in your care has growth hormone deficiency.
- Your doctor should monitor you or the child in your care for high blood sugar levels (hyperglycaemia) during treatment with Ngenla. If you or the child in your care are treated with insulin or other diabetes medicines, your doctor may need to adjust the insulin dose. If you or the child in your care have diabetes and associated severe/worsening eye disease you or the child in your care should not be treated with Ngenla.
- If you or the child in your care have ever had any kind of tumour (cancer).
- If you or the child in your care experience changes in vision, severe or frequent headaches, associated with feeling sick (nausea), vomiting, or experience lack of muscle control 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 your doctor immediately. These could be signs of a temporary increase in pressure within the brain (intracranial hypertension).
- If you or the child in your care are seriously ill (for example, complications following open heart surgery, abdominal surgery, acute respiratory failure, multiple accidental trauma or similar conditions). If you or the child in your care 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 or the child in your care use growth hormone.
- If you or the child in your care develop a severe stomach ache during treatment with Ngenla as this could be a symptom of inflammation of the pancreas.
- If you or the child in your care notice a sideways curvature in your spine (scoliosis), you or the child in your care will need to be checked often by your doctor.
- If during growing you or the child in your care develop a limp or hip or knee pain, you or the child in your care should consult your doctor right away. These could be symptoms of bone disorders in your hip as this may happen during periods of rapid growth.
- If you or the child in your care are taking or stop taking oral contraception or hormonal replacement therapy with oestrogen, your doctor may recommend the dose of Ngenla to be adjusted.

Other medicines and Ngenla
Tell your doctor, pharmacist or nurse if you or the child in your care are using, have recently used or might use any other medicines.
- If you or the child in your care take replacement therapy with corticosteroid medicines (glucocorticoids), as these may reduce the effect of Ngenla on growth. You or the child in your care should consult your doctor regularly, as you or the child in your care may need adjustment of your glucocorticoid dose.
- If you or the child in your care are treated with insulin or other diabetes medicines, you should consult with your doctor as you or your doctor may need to adjust the dose.
- If you or the child in your care are receiving treatment with thyroid hormones, your doctor may need to adjust the dose.
- If you or the child in your care are receiving oestrogen taken orally, you should consult your doctor as you or the child may need to adjust your dose of Ngenla.
- If you or the child in your care are receiving ciclosporin (a medicine that weakens the immune system after transplantation), you should consult your doctor as your doctor may need to adjust the dose.
- If you or the child in your care are receiving medicines to control epilepsy (anticonvulsants), you should consult your doctor as your doctor may need to adjust the dose.

Pregnancy and breast-feeding
If you or the child in your care are pregnant or breast-feeding, think you or the child in your care may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Ngenla has not been tested in pregnant women and it is not known if this medicine can harm your unborn baby. It is therefore preferable to avoid Ngenla during pregnancy. If you are able to get pregnant, you should not use Ngenla unless you are also using reliable contraception.

It is not known whether somatrogon can pass into breast milk. Tell your doctor or the doctor of the child in your care, if you or the child in your care are breast-feeding or plan to do so. Your doctor will then help you or the child in your care decide whether to stop breast-feeding, or whether to stop taking Ngenla, considering the benefit of breast-feeding to the baby and the benefit of Ngenla to you or the child in your care.

Driving and using machines
Ngenla does not affect the ability to drive and use machines.

Ngenla contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially ‘sodium-free’.

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

3. How to use Ngenla

This medicine will only be prescribed by a doctor who has experience with growth hormone treatment and who has confirmed your diagnosis or that of the child in your care.

Always use this medicine exactly as your doctor has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The dose of Ngenla to be injected will be decided by your doctor.

How much to use
Your doctor will work out your dose of Ngenla from your body weight in kilograms. The recommended dose is 0.66 mg per kg body weight and is given once weekly. If you or the child in your care have been previously treated with daily growth hormone injections, your doctor will tell you to wait before taking the first dose of Ngenla until the day after your last daily injection and then continue with Ngenla once each week.

Do not change your dose unless your doctor has told you to.

How Ngenla is given
- Ngenla is available as a pre-filled pen in 2 different sizes (Ngenla 24 mg and Ngenla 60 mg). Based on the recommended dose your doctor or the doctor of the child in your care will prescribe the most appropriate pen size (see section 6 "Contents of the pack and other information").
- Before you or the child in your care use the pen for the first time, your/their doctor or nurse will show you how to use it. Ngenla is given as an injection under the skin (subcutaneous injection) using a pre-filled pen. Do not inject it into a vein or muscle.
- The best place to give Ngenla is in the abdomen (belly), thighs, buttocks or upper arms. Injections to the upper arms and buttocks should be given by the caregiver.
- Change the site of injection on your body, or on the body of the child in your care, each time a dose is administered. .
- If more than one injection is required to deliver a complete dose, each should be administered at a different injection site.

Detailed instructions for use of the pre-filled pen are at the end of this leaflet.

When to use Ngenla
You or the child in your care should use this medicine once a week on the same day each week.

You or the child in your care should record which day of the week you use Ngenla to help you or the child in your care remember to inject this medicine once a week.

If necessary you or the child in your care can change the day of your/their weekly injection as long as it has been at least 3 days since you or the child in your care had your/their last injection. After selecting a new dosing day, continue giving yourself or the child in your care the injection on that day each week.

If you use more Ngenla than you should
If you or the child in your care have injected more Ngenla than you should have been given, contact your doctor straight away as your/their blood sugar levels may need to be checked.

If you forget to use Ngenla
If you or the child in your care forgot to inject a dose and:
- It is 3 days or less since you or the child in your care should have used Ngenla, use it as soon as you remember. Then inject your/their next dose on your/their usual injection day.
- It is more than 3 days since you or the child in your care should have used Ngenla, skip the missed dose. Then inject your/their next dose as usual on your/their next scheduled day. A regular dosing day should be maintained.

Do not use a double dose to make up for a forgotten dose.

If you stop using Ngenla
Do not stop using this medicine without talking to your doctor.

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

4. Possible side effects

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

Very common: may affect more than 1 in 10 people
- Headache
- Bleeding, inflammation, itching, pain, redness, soreness, stinging, tenderness, or warmth at the injection site (injection site reactions)
- Fever (pyrexia)

Common: may affect up to 1 in 10 people
- Decrease in the number of red blood cells in the blood (anaemia)
- Increase in the number of eosinophils in the blood (eosinophilia)
- Decrease in the blood level of thyroid hormone (hypothyroidism)
- Allergic inflammation of the conjunctiva, the clear layer over the outside of the eye (allergic conjunctivitis)
- Joint pain (arthralgia)
- Pain in arms or legs

Uncommon: may affect up to 1 in 100 people
- The adrenal glands do not make enough steroid hormones (adrenal insufficiency)
- Rash

Other possible side effects not seen with Ngenla but which have been reported in other growth hormone medicines treatment may include the following:
- Tissue growth (non cancerous or cancer)
- 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 diarrhoea)

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

Reporting of side effects
If you or the child in your care get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ngenla

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the pen label and on the carton after 'EXP.' The expiry date refers to the last day of that month.

The pre-filled pen should not be used more than 28 days after first use.

Before first use of Ngenla
- Store in a refrigerator (2 °C - 8 °C).
- Keep Ngenla in the outer carton in order to protect from light.
- Remove Ngenla from the refrigerator prior to use. Ngenla may be held at room temperature (up to 32 °C) for up to 4 hours.
- Do not use this medicine if you notice that the solution is cloudy or dark yellow. Do not use the medicine if it has flakes or particles.
- 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.
- Keep 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 last dose, even if it contains unused medicine.
- 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 again after each use.
- Do not leave at room temperature for more than 4 hours with each use.
- Do not put the pen anywhere that the temperature goes above 32 °C.
- If it has been more than 28 days after first use of your pen, get rid of it even if it contains unused medicine. If your pen or the pen of the child in your care 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 a total of 5 times, get rid of it even if it contains unused medicine.

To help you remember when to dispose of your pen you can write the date of first use on the pen label.

A small amount of medicine may remain in the pen after all doses have been correctly given. Do not try to use any remaining medicine. After the last dose is given, the pen must be properly thrown away.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Ngenla contains
- The active substance is somatrogon.

Ngenla 24 mg solution for injection in pre-filled pen
One mL of solution contains 20 mg of somatrogon.
Each pre-filled pen contains 24 mg somatrogon in 1.2 mL of solution. Each pre-filled pen delivers doses from 0.2 mg to 12 mg in a single injection in 0.2 mg increments.

Ngenla 60 mg solution for injection in pre-filled pen
One mL of solution contains 50 mg of somatrogon.
Each pre-filled pen contains 60 mg somatrogon in 1.2 mL solution. Each pre-filled pen delivers doses from 0.5 mg to 30 mg in a single injection in 0.5 mg increments.

- The other ingredients are: trisodium citrate dihydrate, citric acid monohydrate, L-Histidine, sodium chloride (see section 2 “Ngenla contains sodium”), poloxamer 188, m-Cresol, water for injections.

What Ngenla looks like and contents of the pack
Ngenla is a clear and colourless to slightly light yellow solution for injection (injection) in a pre-filled pen.

Ngenla 24 mg solution for injection is available in a pack size containing 1 pre-filled pen. The pen cap, dose button, and label on the pen are coloured lilac.

Ngenla 60 mg solution for injection is available in a pack size containing 1 pre-filled pen. The pen cap, dose button, and label on the pen are coloured blue.

Marketing Authorisation Holder
Pfizer Limited,
Ramsgate Road,
Sandwich,
Kent CT13 9NJ,
United Kingdom

Manufacturer
Pfizer Manufacturing Belgium NV
Rijksweg 12
2870 Puurs-Sint-Amands,
Belgium

For any information about this medicine, please contact:
Medical Information, Pfizer Ltd, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS.
Telephone 01304 616161.

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Instructions for use
Ngenla 24 mg Pen

Injection for subcutaneous (under the skin) use only

Keep this leaflet. These instructions show step-by-step directions on how to prepare and give a Ngenla injection.

Important information about your Ngenla pen

- Ngenla for injection is a multi-dose pre-filled pen containing 24 mg of medicine.
- Ngenla for injection can be given by a patient, caregiver, doctor, nurse or pharmacist. **Do not** try to inject Ngenla yourself until you are shown the right way to give the injections and read and understand the Instructions for Use. If your doctor, nurse or pharmacist decides that you or a caregiver may be able to give your injections of Ngenla at home, you should receive training on the right way to prepare and inject Ngenla. It is important that you read, understand, and follow these instructions so that you inject Ngenla the right way. It is important to talk to your doctor, nurse or pharmacist to be sure you understand your Ngenla dosing instructions.
- To help you remember when to inject Ngenla, you can mark your calendar ahead of time. Call your doctor, nurse or pharmacist if you or your caregiver have any 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 your dose is more than 12 mg, you will need to give more than 1 injection.
- A small amount of the medicine may remain in the pen after all doses have been correctly given. This is normal. Patients should not try to use the remaining solution but get rid of the pen in the correct way.
- **Do not** share your pen with other people, even if the needle has been changed. You may give other people a serious infection, or get a serious infection from them.
- Always use a new sterile needle for each injection. This will reduce the risk of contamination, infection, leakage of medicine, and blocked needles leading to the wrong dose.
- **Do not** shake your 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 product.

Supplies you will need each time you inject

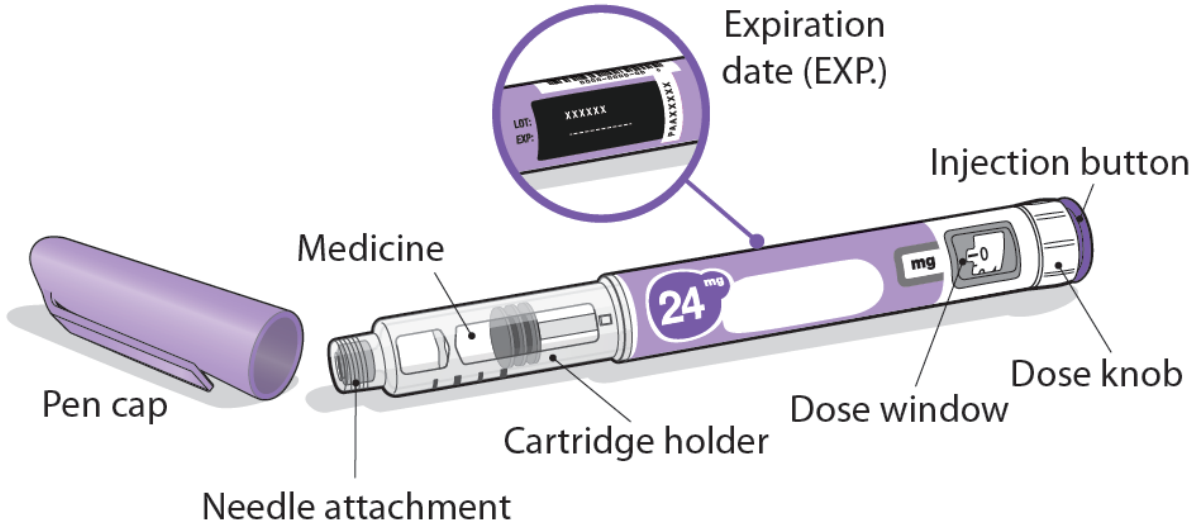
Included in the carton:

- 1 Ngenla 24 mg pen.

Not included in the carton:

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

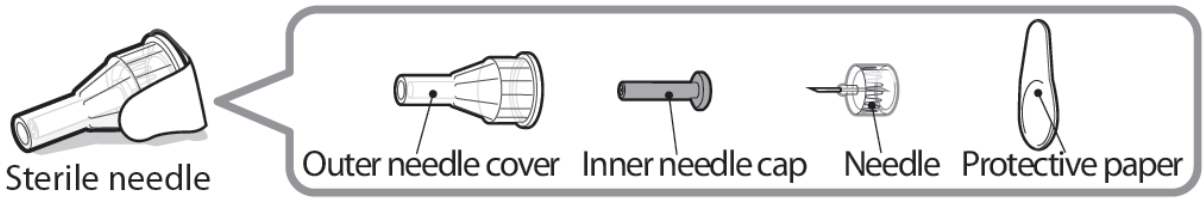
Ngenla 24 mg pen:



Needles to use
Pen needles are **not included** with your Ngenla pen. You can use pen needles from 4 mm to 8 mm and between 30G and 32G.

- The following needles have been shown to be compatible with your Ngenla pen:
  - 32G (Novo Nordisk®, NovoFine® Plus)
  - 31G (Novo Nordisk®, NovoFine®)
  - 31G (Becton Dickinson and Company, BD Ultra-Fine™ or BD Micro-Fine™)
- The following needles with safety shield have been shown to be compatible with your Ngenla pen:
  - 30G (Becton Dickinson and Company, AutoShield Duo™)
  - 30G (Novo Nordisk®, NovoFine® AutoCover®)
- Talk with your doctor, nurse or pharmacist about the right needle for you.

Sterile needle (example) not supplied:



Note: Needles with safety shield do not have an inner needle cap. Steps 5, 6 and 11 within these instructions relating to the inner needle cap may not apply when using a needle with safety shield. Refer to the needle manufacturer's instructions for use for more information.

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 your pen until you are ready for your injection.

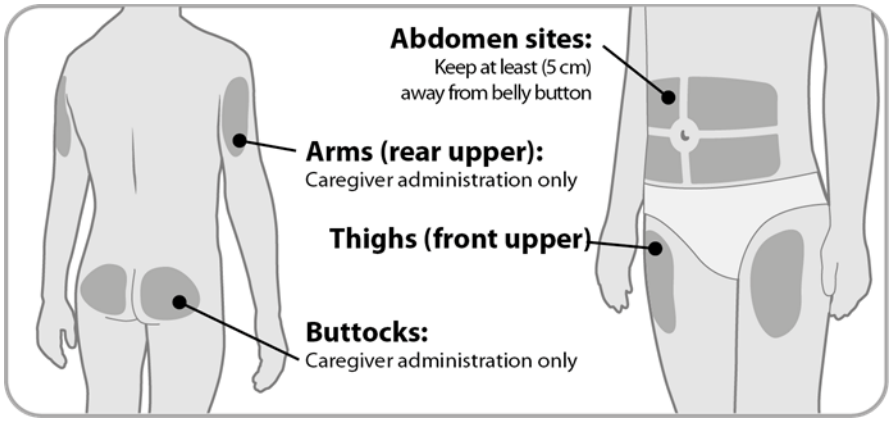
Preparing for your injection

Step 1 Getting ready

- Wash and dry your hands.

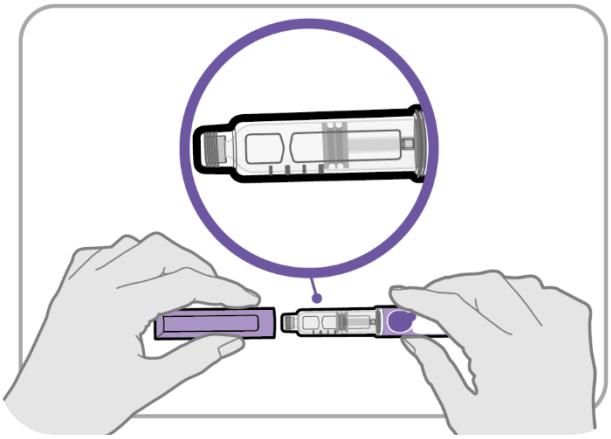
- You can use your pen straight from the refrigerator. For a more comfortable injection, leave your pen at room temperature for up to 30 minutes. **(See section 5 "How to store Ngenla" of the Ngenla 24 mg pre-filled pen Package Leaflet).**
- Check the name, strength, and label of your pen to make sure it is the medicine your doctor has prescribed for you.
- Check the expiry date on the pen label. **Do not** use if the expiry date has passed.
- **Do not** use your pen if:
    - it has been frozen or exposed to heat (above 32 °C) or it has been more than 28 days after first use of the pen. **(See section 5 "How to store Ngenla" of the Ngenla 24 mg pre-filled pen Package Leaflet).**
    - it has been dropped
    - it looks broken or damaged
- **Do not** remove the pen cap from your pen - until you are ready to inject.

Step 2 Choose and clean your injection site



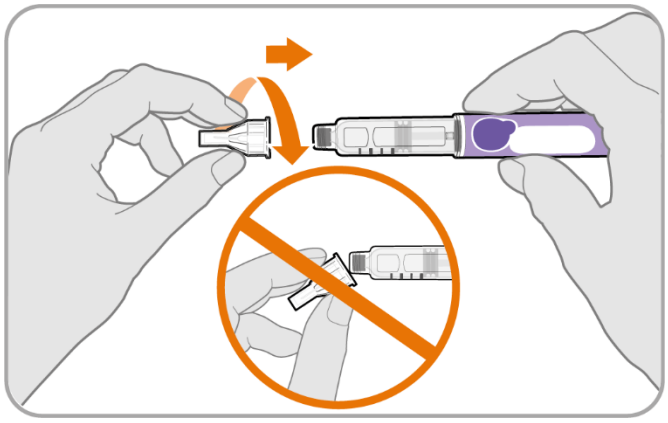
- Ngenla can be given in the abdomen (belly), thighs, buttocks, or upper arms.
- Choose the best place to inject, as recommended by your doctor, nurse or pharmacist.
- If more than 1 injection is needed to complete your full dose, each injection should be given in a different injection site.
- **Do not** inject into bony areas, areas that are bruised, red, sore or hard, and areas that have scars or skin conditions.
- Clean the injection site with an alcohol swab.
- Allow the injection site to dry.
- **Do not** touch injection site after cleaning.

Step 3 Check medicine



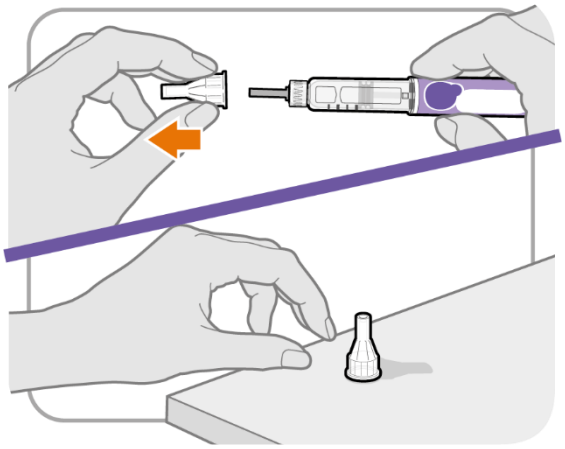
- Pull off the pen cap and keep it for after your injection.
- Check the medicine inside the cartridge holder.
- Make sure the medicine is clear and colourless to slightly light yellow. **Do not** inject the medicine if it is cloudy or dark yellow.
- Make sure the medicine is free of flakes or particles. **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 Attach needle



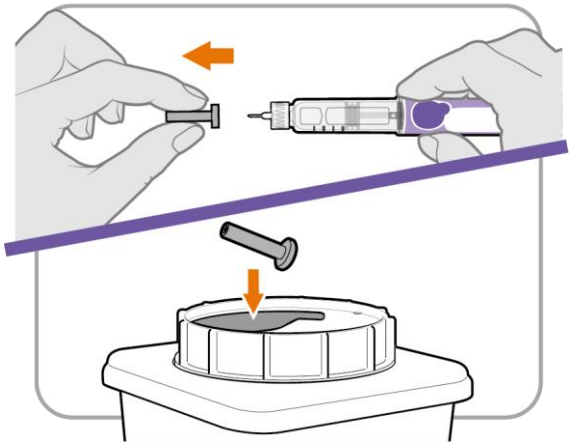
- Take a new needle and pull off the protective paper.
- Line the needle up with your pen keeping them both straight.
- Gently push and then screw the needle onto your pen.
  Do not over tighten.
  Note: Be careful not to attach the needle at an angle. This may cause the pen to leak.
  Caution: Needles have sharp tips at both ends. Handle with care to make sure you do not prick yourself (or anyone else) with the needle.

Step 5 Pull off outer needle cover

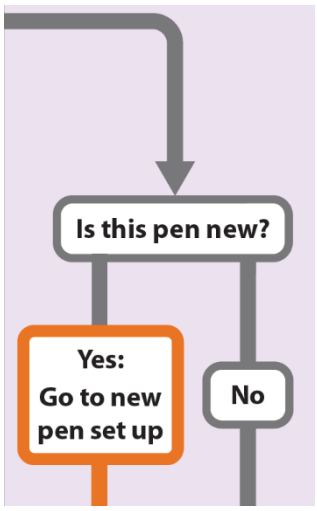


- Pull off the outer needle cover.
- Make sure you keep the outer needle cover. You will need it later to remove the needle.
  Note: You should see an inner needle cap after you have removed the outer cover. If you do not see this, try to attach the needle again.
  Note: If using needle with safety shield, refer to the manufacturer's instructions for use.

Step 6 Pull off inner needle cap



- Pull off the inner needle cap carefully to show the needle.
- Throw away the inner needle cap in a sharps container. It is not needed again.
  Note: If using needle with safety shield, refer to the manufacturer's instructions for use.



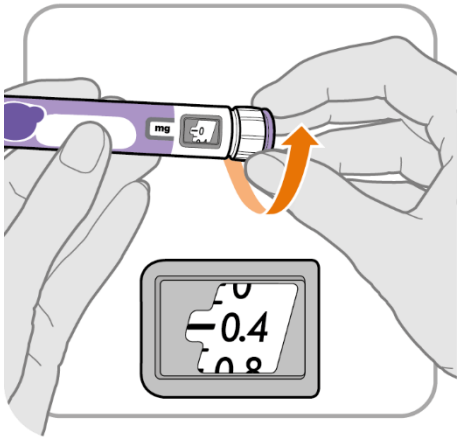
('Yes: Go to new pen set up' has an arrow directing to 'New pen set up (priming)' and 'No' has an arrow directing to 'Setting your prescribed dose')

New pen set up (priming) – for the first use of a new pen only

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

- New pen set up is done before each new pen is used for the first time.
- The purpose of setting up a new pen is to remove air bubbles and make sure you get the correct dose.
  Important: Skip Step-A through to Step-C if you have already set up your pen.

Step-A: Set knob to 0.4

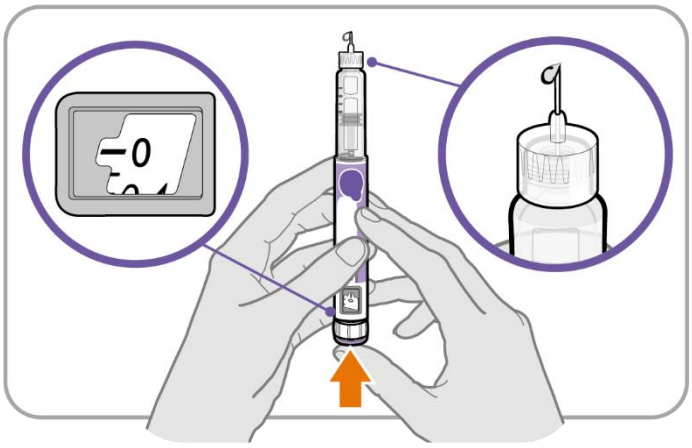


- Turn the dose knob to **0.4**.
  Note: If you turn the dose knob too far, you can turn it back.

Step-B: Tap cartridge holder

- Hold the pen with the needle pointing up so that the air bubbles can rise.
- **Tap** the cartridge holder gently to float any air bubbles to the top.
  Important: Follow Step-B even if you do not see air bubbles.

Step-C: Press button and check for liquid

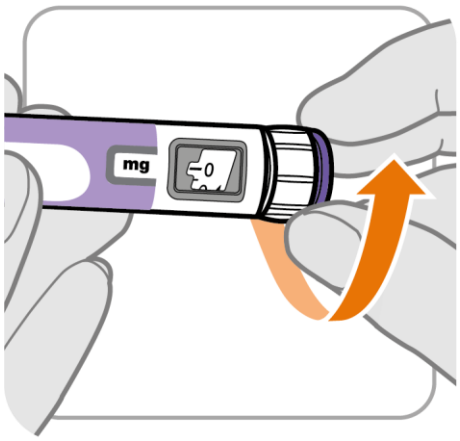


- **Press the injection button** until it cannot go any further and **"0"** is shown in the dose window.
- **Check** for liquid at the needle tip. If liquid appears, your pen is set up.
- Always make sure that a drop of liquid appears before you inject. If liquid has not appeared, repeat Step-A through to Step-C.
    - If liquid does not appear after you have repeated Step-A through Step-C five (5) times, attach a new needle and try one (1) more time.

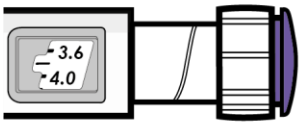
  Do not use the pen if a drop of liquid still does not appear. Contact your doctor, nurse or pharmacist, and use a new pen.

Setting your prescribed dose

Step 7 Set your dose

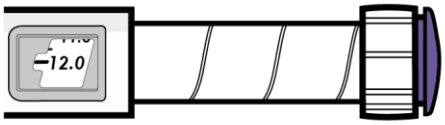


Example A:



3.8 mg shown in the dose window

Example B:



12.0 mg shown in the dose window

- Turn the dose knob to set your 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.
    - Your pen contains 24 mg of medicine but you can only set a dose of up to 12 mg 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 you have set the correct dose.**
  Important: Do not press the injection button while setting your dose.

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

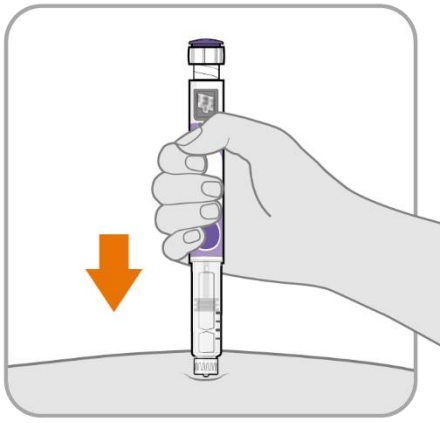
- If your dose is more than 12 mg you will need more than 1 injection.
- You can give from 0.2 mg to 12 mg in a single injection.
    - If you need help dividing up your dose the right way, ask your doctor, nurse or pharmacist.
    - Use a new needle for each injection **(See Step 4: Attach needle)**.
    - If you normally need to give 2 injections for your full dose, be sure to give your second dose.

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

- If your 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 your pen for your full dose, you may either:
    - inject the amount left in your pen, then prepare a new pen to complete your dose in full.
      Remember to subtract the dose you have already received. For example, if the dose is 3.8 mg and you can only set the dose knob to 1.8 mg, you should inject another 2.0 mg with a new pen.
    - or get a new pen and inject the full dose.

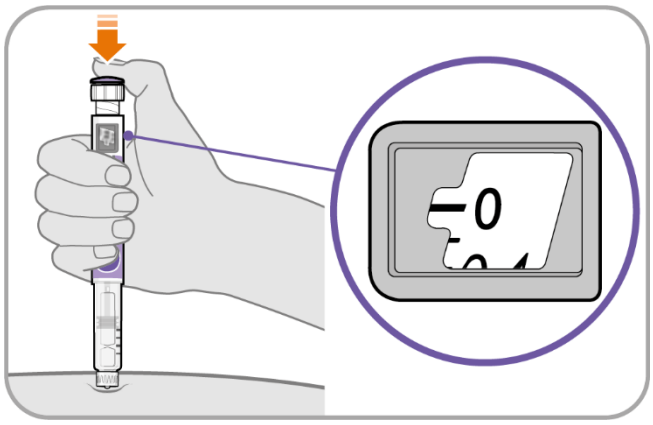
Injecting your dose

Step 8 Insert the needle



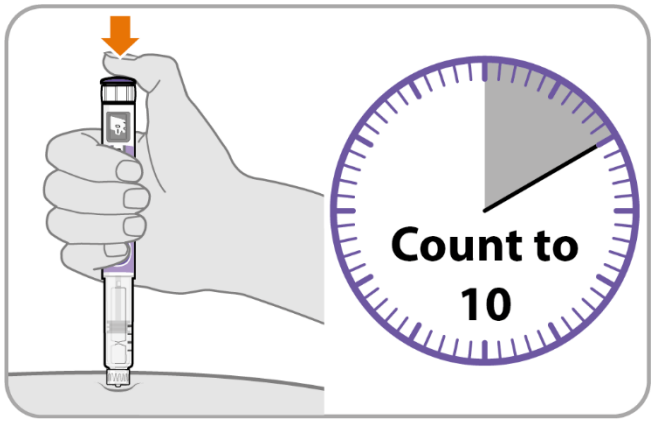
- Hold your pen so you can see the numbers in the dose window.
- Insert the needle straight into your skin.

Step 9 Inject your medicine



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

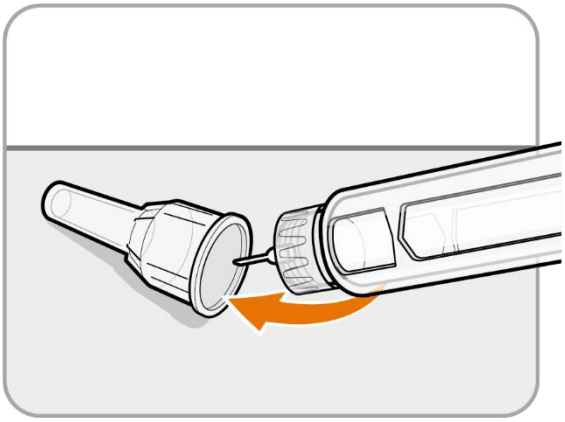
Step 10 Count to 10



- **Continue to press the injection button while counting to 10**. Counting to 10 will allow the full dose of medicine to be given.
- After counting to 10, let go of the injection button and slowly remove the pen from the injection site by pulling the needle **straight out.**

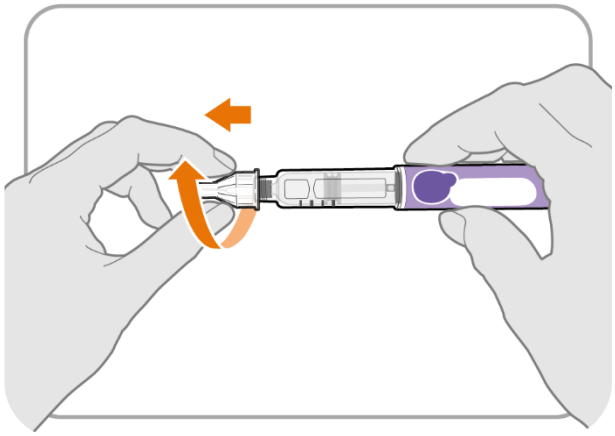
Note: You may see a drop of medicine at the needle tip. This is normal and does not affect the dose you just received.

Step 11 Attach outer needle cover



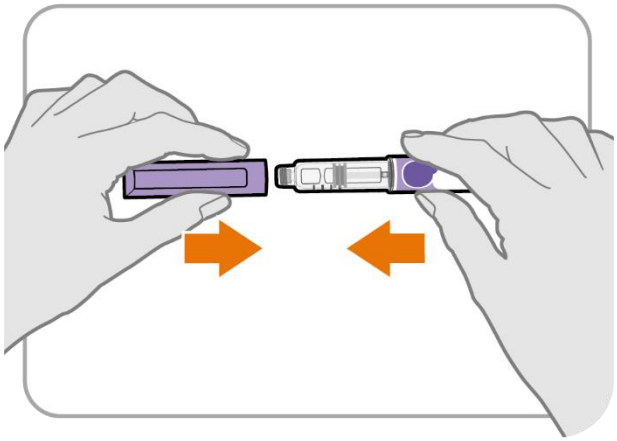
- Carefully place the outer needle cover back on the needle.
- Press on the outer needle cover until it is secure.
  Caution: Never try to put the inner needle cap back on the needle. You may prick yourself with the needle.
  Note: If using needle with safety shield, refer to manufacturer's instructions for use.

Step 12 Remove the needle



- Unscrew the needle from the pen.
- Gently pull until the needle comes off.
  Note: If the needle is still on, replace the outer needle cover and try again. Be sure to apply pressure when unscrewing the needle.
  Dispose of your used pen needles in a sharps container as instructed by your doctor, nurse or pharmacist and in accordance with local health and safety laws. Keep the sharps container out of the reach of children. **Do not** reuse needles.

Step 13 Replace the pen cap



- Replace the pen cap back onto your pen.
- **Do not** recap the pen with a needle attached.
- If there is any medicine left in your pen, store in the refrigerator between uses. **(See section 5 "How to store Ngenla" of the Ngenla 24 mg pre-filled pen Package Leaflet)**.

Step 14 After your 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.
- You may cover the injection site with a small adhesive bandage, if needed.
- If your pen is empty or it has been **more than 28 days** after first use, throw it away even if it contains unused medicine. Throw away your pen in the sharps container.
- To help you remember when to dispose of your pen you can write the date of first use on the pen label and below:

Date of first use _____ / _____ / _____