NGENLA®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

1. Why am I using NGENLA?

NGENLA contains the active ingredient somatrogon. NGENLA is used to improve growth in children who are not growing at the expected rate for their age because they have low levels of growth hormone.

For more information, see Section 1. Why am I using NGENLA? in the full CMI.

2. What should I know before I use NGENLA?

Do not use NGENLA if you have ever had an allergic reaction to somatrogon or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use NGENLA? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with NGENLA and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use NGENLA?

- NGENLA comes in two different dosage strengths. Your doctor will prescribe the dose of medicine and dosage strength that is right for you.
- Your doctor, nurse or pharmacist will show you and/or your caregiver how to inject NGENLA before you use it for the first time.

More instructions can be found in Section 4. How do I use NGENLA? in the full CMI.

5. What should I know while using NGENLA?

Things you should do	• Call your doctor if you experience nausea, vomiting, headaches, problems with your vision, limping, pain in the hips and/or knees. • Remind any doctor or dentist you visit that you are using NGENLA.
Things you should not do	• Do not shake your NGENLA pen, shaking can damage the medicine. • Do not share your NGENLA pens and needles with another person, even if the needle has been changed. You may give the other person an infection or you may get an infection from them. • Do not use NGENLA more than once a week.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how NGENLA affects you.
Looking after your medicine	• Store NGENLA pens in the refrigerator (2°C to 8°C) and away from direct sunlight. Do not freeze your pen or expose it to heat. Do not store the pen with the needle attached and keep the pen cap on the pen when it is not in use.

For more information, see Section 5. What should I know while using NGENLA? in the full CMI.

6. Are there any side effects?

Common side effects are reactions at the site of the injection, headache, fever, low red blood cell count (anaemia), increased eosinophil (a type of white blood cell) count, underactive thyroid (hypothyroidism), allergic conjunctivitis, joint pain, and pain in the legs and arms. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ 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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

NGENLA®

Active ingredient: somatrogon

Consumer Medicine Information (CMI)

This leaflet provides important information about using NGENLA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using NGENLA.**

Where to find information in this leaflet:

1. Why am I using NGENLA?

NGENLA contains the active ingredient somatrogon. NGENLA is a prescription medicine that contains a modified form of human growth hormone.

NGENLA is used to improve growth in children who are not growing at the expected rate for their age, because they have low levels of growth hormone.

Medicines are sometimes prescribed for purposes other than those listed in this leaflet. Do not use NGENLA for a condition for which it was not prescribed.

2. What should I know before I use NGENLA?

Warnings

Do not use NGENLA if:

- You are allergic to somatrogon, or any of the ingredients listed at the end of this leaflet. Symptoms of an allergic reaction may include chest tightness, shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue, throat or other parts of the body, hives, itching or severe skin rash. Always check the ingredients to make sure you can use this medicine.

Your doctor will not prescribe NGENLA if you:

- have an active tumour or evidence of cancer growth or are currently being treated for cancer.
- have a serious illness following open heart or stomach surgery, or due to multiple injuries or respiratory failure (your lungs can't get enough oxygen into your blood).
- have Prader-Willi syndrome without a diagnosis of growth hormone deficiency.
- are a child and have closed epiphyses (this means that your bones are no longer growing).

Tell your doctor if you:

- have any other medical conditions (diabetes, thyroid disease, adrenocortical insufficiency (also known as ACTH deficiency)).
- take medicines for any other condition.
- your liver or kidneys do not work as well as expected.
- experience muscle pain or disproportionate pain at the injection site.

Your doctor should monitor you for high blood sugar levels (hyperglycaemia) and signs and symptoms of other medical conditions (benign intracranial hypertension, curvature of the spine) during treatment with NGENLA. If you are treated with insulin, your doctor may need to adjust your insulin dose.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with NGENLA and affect how it works.

Tell your doctor if you are taking:

- Any medicine (including insulin) for the treatment of diabetes.

- Glucocorticoids (commonly called steroids) such as cortisone and prednisone

Check with your doctor or pharmacist if you are not sure what medicines, vitamins or supplements you are taking and if these affect NGENLA.

4. How do I use NGENLA?

How much to use

- NGENLA comes in two different dosage strengths. Your doctor will prescribe the dose of medicine and dosage strength that is right for you.
- Your doctor, nurse or pharmacist will show you and/or your caregiver how to inject NGENLA before you use it for the first time. Do not try to inject NGENLA until you and/or your caregiver have been shown the correct way by your doctor, nurse or pharmacist.
- Follow the instructions provided and use NGENLA until your doctor tells you to stop.

When to use NGENLA

- NGENLA should be used once a week, on the same day each week, at any time of the day.
- You should record which day of the week NGENLA is used to help you remember to inject this medicine once a week.
- You may change the day of the week you use NGENLA as long as your last dose was given 3 or more days before.

How to use NGENLA

- NGENLA is given by injection under the skin (subcutaneous) of the abdomen (stomach), thighs, buttocks or upper arms.
- Do not inject NGENLA into a muscle or vein.
- Change the site of injection each week.
- If more than one injection is needed to complete your full dose, each injection should be given at a different injection site.
- You and/or your caregiver should review the detailed Instructions for Use provided in the pack on the correct way to prepare and give an injection of NGENLA.

If you forget to use NGENLA

NGENLA should be used regularly at the same time each week. If you miss your dose at the usual time, give the missed dose as soon as possible within 3 days of the missed dose.

If more than 3 days have passed, skip the dose you missed and give your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you use too much NGENLA

If you think that you have used too much NGENLA you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using NGENLA?

Things you should do

Call your doctor as soon as possible if you experience any of the following:

- nausea, vomiting, headaches or problems with your vision.
- limping.
- pain in the hips and/or knees.

Remind any doctor or dentist you visit that you are using NGENLA.

Things you should not do

- Do not shake your pen, shaking can damage the medicine.
- Do not share your NGENLA pens and needles with another person, even if the needle has been changed. You may give the other person an infection or you may get an infection from them.
- Do not use NGENLA more than once a week.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how NGENLA affects you.

Looking after your medicine

Follow the instructions on the carton on how to take care of your medicine properly.

Store NGENLA pens in the refrigerator (2°C to 8°C) and away from direct sunlight. Do not freeze your pen or expose it to heat.

Do not store the pen with the needle attached and keep the pen cap on the pen when it is not in use.

Do not use this medicine after the expiry date, or if it has been more than 28 days after first use, or if the same pen has been used 5 times, or if the pen has been exposed to temperatures above 32°C, or if the pen has been left out of the refrigerator for more than two hours with each use.

Keep it where young children cannot reach it.

Travelling with your medicine

When travelling, transport your pen in its original carton in an insulated container with an ice pack. To avoid freezing, make sure your pen does not touch the ice pack. Once you arrive, place your pen in a refrigerator as soon as possible. Do not leave it in a car or other place where it can get too hot or too cold.

When to discard your medicine

If your pen is empty, or it has been more than 28 days after first use, or if the same pen has been used 5 times, or if the pen has been exposed to temperatures above 32°C, or if the pen has been left out of the refrigerator for

more than 2 hours with each use, discard it even if it contains unused medicine.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side effects	What to do
Reactions at the site of the injection • Pain or bruising • Bleeding • Redness (erythema) • Itching (pruritis) alone or with a rash (urticaria) • Swelling • Warmth • Local thickening of the skin (induration) • Raised skin (hypertrophy) **Blood and lymphatic system disorders** • Low red blood cell count (anaemia) • Increased eosinophil (a type of white blood cell) count (eosinophilia) **Endocrine disorders** • Underactive thyroid (hypothyroidism) **Eye disorders** • Allergic conjunctivitis **General disorders** • Fever **Musculoskeletal and connective tissue disorders** • Joint pain • Pain in the arms or legs **Nervous system disorders** • Headache **Skin and subcutaneous tissue disorders** • Generalised rash	**Speak to your doctor if you have any of these side effects and they worry you.**

Serious side effects	What to do
Allergic type reactions • Severe shortness of breath, severe wheezing severe difficulty breathing, severe coughing • Swelling of the face, lips, tongue or throat which may cause difficulty in swallowing or breathing • Swelling of the hands, feet or ankles • Hives, itching or severe skin rash **Endocrine disorders** • Fatigue, muscle weakness, decreased appetite, weight loss and abdominal pain (common symptoms of adrenal insufficiency)	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

NGENLA contains a preservative called metacresol. In very rare cases the presence of metacresol can cause inflammation (swelling) in muscles. Tell your doctor if you experience muscle pain or disproportionate pain at the injection site.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration (TGA) online at www.tga.gov.au/safety/reporting-problems. By reporting side effects, you can help provide more information on the safety of NGENLA.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What NGENLA contains

Active ingredient (main ingredient)	somatrogon
Other ingredients (inactive ingredients)	Citric acid monohydrate; histidine; metacresol (preservative); poloxamer; sodium citrate dihydrate; sodium chloride; water for injections.

Do not use this medicine if you are allergic to any of these ingredients. Talk to your doctor if you are unsure.

What NGENLA looks like

NGENLA comes as a clear and colourless to slightly light-yellow solution contained in a glass cartridge that is enclosed in a disposable pre-filled pen.

The NGENLA 24 mg pen has a lilac colour cap, injection button and label. The NGENLA 60 mg pen has a blue colour cap, injection button and label.

NGENLA 24 mg Aust R 349990.

NGENLA 60 mg Aust R 350035.

Who distributes NGENLA

Pfizer Australia Pty Ltd

Sydney NSW

Toll free number: 1800 675 229

www.pfizermedicalinformation.com.au

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