

GENOTROPIN®

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.

1. Why am I using GENOTROPIN?

GENOTROPIN contains the active ingredient somatropin. GENOTROPIN is used to treat short stature caused by the lack of growth hormone, reduced growth in girls with Turner syndrome, children with Prader-Willi syndrome, children with kidney disease to help them grow at a normal rate, and adults who do not produce enough natural growth hormone.

For more information, see Section [1. Why am I using GENOTROPIN?](#) in the full CMI.

2. What should I know before I use GENOTROPIN?

Do not use GENOTROPIN if you have ever had an allergic reaction to somatropin, metacresol 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 GENOTROPIN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with GENOTROPIN 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 GENOTROPIN?

- GENOTROPIN comes in two different dosage strengths. Your doctor will prescribe the dose of medicine and dosage strength that is right for you.
- You will be taught how to mix and inject GENOTROPIN before you use it for the first time.

More instructions can be found in Section [4. How do I use GENOTROPIN?](#) in the full CMI.

5. What should I know while using GENOTROPIN?

Things you should do	<ul style="list-style-type: none">• Call your doctor if you experience nausea, vomiting, headaches,
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	<p>problems with your vision, limping, pain in the hips and/or knees.</p> <ul style="list-style-type: none"> • Remind any doctor, dentist or pharmacist you visit that you are using GENOTROPIN.
Things you should not do	<ul style="list-style-type: none"> • Do not stop using this medicine without your doctor's permission and do not miss injections regularly. • Do not shake your pen, shaking can damage the medicine.
Driving or using machines	<ul style="list-style-type: none"> • Be careful before you drive or use any machines or tools until you know how GENOTROPIN affects you.
Looking after your medicine	<ul style="list-style-type: none"> • Store GENOTROPIN in the refrigerator at 2-8°C protected from light. Do not freeze it or expose it to heat above 25°C. • Do not store the pen with the needle attached.

For more information, see Section [5. What should I know while using GENOTROPIN?](#) in the full CMI.

6. Are there any side effects?

Common side effects are reactions at the injection site, painful joints, muscle aches and pains, muscle stiffness and swelling of the arms or legs. Side effects such as severe or recurring headaches, problems with your vision, nausea or vomiting, extreme tiredness, change to thirst or appetite, increased need to pass urine, limping, discomfort or pain in the hip or knee, and curvature of the spine can be serious and you may need medical attention. These side effects are rare.

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.

GENOTROPIN®

Active ingredient(s): *somatropin (rbe), recombinant growth hormone*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

- [1. Why am I using GENOTROPIN?](#)
- [2. What should I know before I use GENOTROPIN?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use GENOTROPIN?](#)
- [5. What should I know while using GENOTROPIN?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using GENOTROPIN?

GENOTROPIN contains the active ingredient somatropin (recombinant human growth hormone, or biosynthetic human growth hormone). It is a man-made substance which is produced in a laboratory.

GENOTROPIN is used to treat:

- Short stature caused by the lack of growth hormone.
GENOTROPIN promotes the growth of the long bones (for example, upper legs) in children with reduced height due to lower than normal levels of growth hormone.

- Reduced growth in girls with Turner syndrome.
Turner syndrome is a genetic disorder found in females. The condition may cause short stature and ovaries to not fully develop.

- Children with Prader-Willi syndrome.
Prader-Willi syndrome is a genetic disorder that may cause short stature, low muscle tone and a constant feeling of hunger.

GENOTROPIN helps to improve growth and body composition. It also helps to reduce excessive fat and improve muscle mass.

Diet restrictions may still be necessary during treatment with GENOTROPIN.

- Children with kidney disease, to help them grow at a normal rate.
- Adults who do not produce enough natural growth hormone.

However, your doctor may prescribe GENOTROPIN for another purpose. Ask your doctor if you have any questions about why GENOTROPIN has been prescribed for you.

2. What should I know before I use GENOTROPIN?

Warnings

Do not use GENOTROPIN if:

- you are allergic to somatotropin, metacresol (a preservative in the GENOTROPIN mixing fluid) or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Your doctor will not prescribe GENOTROPIN if you:

- are a child and have closed epiphyses (this means that your bones have finished growing)
- have an active tumour (cancer) or evidence of cancer growth
- are currently being treated for cancer
- have a serious injury or illness, or surgical procedures, requiring intensive care
- have Prader-Willi syndrome and are severely overweight or have marked difficulty breathing.

Tell your doctor if you:

- have or have had other medical conditions (diabetes mellitus, cancer, a kidney transplant, thyroid disease,

adrenocortical insufficiency (also known as ACTH deficiency))

- take medicines for any other condition.

Your doctor should monitor you for glucose intolerance during treatment with GENOTROPIN. 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

Tell your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known whether GENOTROPIN passes into breast milk.

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 GENOTROPIN and affect how it works.

Tell your doctor if you are taking:

- any medicine (including insulin) for the treatment of diabetes
- thyroxine (thyroid hormone) for the treatment of thyroid deficiency
- replacement therapy for ACTH deficiency e.g. hydrocortisone or fludrocortisone
- corticosteroids such as cortisol or dexamethasone e.g. for the treatment of severe asthma, some skin conditions or rheumatoid arthritis
- epilepsy medicines, e.g. carbamazepine, ethosuximide or tiagabine
- ciclosporin e.g. for the treatment of severe skin disease (psoriasis), rheumatoid arthritis or after transplant surgery
- hormone therapy e.g. HRT for oestrogen deficiency, menopause or osteoporosis (bone thinning), testosterone for hormone deficiency in men, or other hormone therapy for contraception ("the Pill"), endometriosis or some cancers.

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

4. How do I use GENOTROPIN?

How much to use

- GENOTROPIN comes in two dosage strengths. Your doctor, nurse or pharmacist will tell you how many milligrams (mg) of GENOTROPIN you must use and how often.

- Your doctor, nurse or pharmacist will show you and/or your caregiver how to inject GENOTROPIN before you use it for the first time. Do not try to inject GENOTROPIN until you and/or your caregiver have been shown the correct way by your doctor, nurse or pharmacist.
- Follow the instructions provided and use GENOTROPIN until your doctor tells you to stop.

When to use GENOTROPIN

- GENOTROPIN should be used in the evening if possible. Normally, growth hormone is made by the body at night. Giving the injection at night helps to copy this process.

How to use GENOTROPIN

- GENOTROPIN is given by injection under the skin (sub-cutaneous).
- Use a different injection site every day to prevent wasting of skin fat at the injection site.
- You will be taught how to mix and inject your GENOTROPIN using a disposable pre-filled pen (GENOTROPIN GoQuick®).

When you mix the GENOTROPIN, gently tilt the pen from side to side. Do not shake the pen as this may deactivate the growth hormone. After mixing check to make sure that the powder is completely dissolved and the solution is clear. Do not inject if the solution is cloudy or has particles in it.

You can store GENOTROPIN in a refrigerator at 2-8°C for up to 28 days after it has been mixed.

It is a good idea to refer to the Instructions for Use provided in the pack on the correct way to prepare and inject GENOTROPIN each time you use it.

If you forget to use GENOTROPIN

GENOTROPIN should be used regularly at the same time each day. If you forget to use a dose, have your next injection at the usual time the next day.

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

Tell your doctor, nurse or pharmacist if you forget to use your GENOTROPIN.

If you use too much GENOTROPIN

If you think that you have used too much GENOTROPIN, 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 GENOTROPIN?

Things you should do

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

- rash, wheezing, swelling of the eyelids, face or lips. These may be symptoms of an allergic reaction
- nausea, vomiting, headaches or problems with your vision. These may be symptoms of raised pressure of the fluid around the brain
- limping
- pain in the hips and/or knees.

Tell your doctor if you:

- become pregnant while you are using GENOTROPIN
- start to have difficulty breathing or start to snore, or have an increase in snoring while you are using GENOTROPIN
- stop or change your oral oestrogen therapy
- stop or change your glucocorticoid therapy
- have concerns about how the product looks e.g. if it looks different from normal.

Remind any doctor, dentist or pharmacist you visit that you are using GENOTROPIN.

Things you should not do

- Do not stop using this medicine without your doctor's permission
- GENOTROPIN should be used strictly according to the instructions you have been given. Do not change your dose unless your doctor has told you to
- Do not miss injections regularly. Missing injections can reduce effectiveness and you risk being taken off growth hormone altogether
- Do not heat or freeze your mixed or unmixed GENOTROPIN
- Do not give your GENOTROPIN to anyone else
- Do not shake the pen, shaking can damage the medicine
- Use all the GENOTROPIN in each pen. Do not discard any unused GENOTROPIN without discussing this with your doctor, nurse or pharmacist
- Do not refill empty pens
- Do not carry the mixed GENOTROPIN in the shirt pocket or school bag. Mixed GENOTROPIN should be stored in the refrigerator at 2-8°C.

Things to be careful of

The instructions for using GENOTROPIN must be followed exactly otherwise problems such as the following may occur:

- loss of GENOTROPIN activity
- broken or jammed pen

- broken cartridge.

If any of these problems occur contact the person who trained you on how to mix your GENOTROPIN.

Driving or using machines

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

Looking after your medicine

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

Store your GENOTROPIN (mixed or unmixed) in the refrigerator at 2-8°C. Do not freeze your pen or expose it to heat above 25°C.

Keep GENOTROPIN in the original packaging during storage. GENOTROPIN needs protection from light.

It is also possible to store your unmixed GENOTROPIN outside the refrigerator, but under 25°C, for one month as long as the expiry date has not passed.

During and/or at the end of the 1 month period, the product should not be put back in the refrigerator. After this it must be discarded.

Take GENOTROPIN out of the refrigerator approximately ½ hour before your injection. This will bring it to room temperature (about 25°C). It is more comfortable to inject at this temperature.

Always remove the injection needle before storing your GENOTROPIN in the refrigerator. This will prevent leakage of GENOTROPIN through the needle.

Keep GENOTROPIN where young children cannot reach it.

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.

Do not use this medicine after the expiry date.

Used needles and empty pens should be disposed of in a Sharps container or similar puncture proof container composed of hard plastic or glass.

Ask your doctor, nurse or pharmacist where you can dispose of the container once it is full.

When you are due for a new supply of GENOTROPIN inform your doctor, nurse or pharmacist of the number of pens that you have remaining.

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

Side effects	What to do
<p>Administration site disorders:</p> <ul style="list-style-type: none">• a reaction at or around the injection site such as bruising, itching, redness or swelling• pain or hardness around the injection site <p>General disorders:</p> <ul style="list-style-type: none">• swelling of the arms or legs• swelling of the face <p>Metabolism and nutrition disorders:</p> <ul style="list-style-type: none">• extreme tiredness or change to thirst or appetite• increased thirst and need to pass urine, particularly if overweight or if anyone in your family has diabetes <p>Musculoskeletal disorders:</p>	<p>Speak to your doctor if you have any of these side effects and they worry you.</p> <p>You must tell your doctor immediately if any of these side effects become serious as you may require medical attention.</p>

Side effects	What to do
<ul style="list-style-type: none"> ● discomfort or pain in the hip or knee ● limping ● curvature of the spine ● painful joints or muscle aches and pains ● unusual muscle stiffness <p>Nervous system disorders:</p> <ul style="list-style-type: none"> ● nausea, vomiting, severe or recurring headaches or problems with your vision ● tingling or numbness in your fingers, hands or feet ● in adults, pain or burning sensation in the hands or underarms (known as Carpal Tunnel Syndrome) <p>Skin disorders:</p> <ul style="list-style-type: none"> ● rash ● itching (pruritis) alone or with a rash (urticaria) 	

There have been very rare reports of leukaemia (a cancer that affects the blood system) developing in children using GENOTROPIN. A causal association of GENOTROPIN with the development of leukaemia has not been identified.

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 online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

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 GENOTROPIN contains

Active ingredient	somatropin
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(main ingredient)	
Other ingredients (inactive ingredients)	glycine, sodium phosphate, mannitol and water for injections
Potential allergens	metacresol

Do not take this medicine if you are allergic to any of these ingredients.

What GENOTROPIN looks like

GENOTROPIN comes in a disposable multidose pre-filled pen (GoQuick) that contains GENOTROPIN in a two-chamber glass cartridge.

The GENOTROPIN GoQuick 5mg pen is colour coded green. The GENOTROPIN GoQuick 12mg pen is colour coded purple.

Prior to mixing, GENOTROPIN is in a powder form in the top chamber and the liquid (diluent) for mixing is in the bottom chamber of the cartridge.

The GENOTROPIN in the GoQuick pen is mixed when you start a new pen.

GENOTROPIN can be identified by the Australian Register Number:

GENOTROPIN GoQuick 5mg: AUST R 166829

GENOTROPIN GoQuick 12mg: AUST R 166831

Who distributes GENOTROPIN

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

This leaflet was prepared in December 2022.