PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

GENOTROPIN® 16 IU (5,3 mg), lyophilised powder and solvent for injection

Somatropin

Contains sugar (41 mg mannitol per mL)

Read all of this leaflet carefully before you are given GENOTROPIN

- Keep this leaflet. You* may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- GENOTROPIN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

**The information in this leaflet is directed to the recipient of GENOTROPIN treatment, this could either be you or your child.*

What is in this leaflet

1. What GENOTROPIN is and what it is used for
2. What you need to know before you use GENOTROPIN
3. How to use GENOTROPIN
4. Possible side effects
5. How to store GENOTROPIN
6. Contents of the pack and other information

1. What GENOTROPIN is and what it is used for

GENOTROPIN is a growth hormone. The somatropin in GENOTROPIN is the same as natural human growth hormone. This hormone is needed for bones and muscles to grow. It also helps your fat and muscle tissues to develop in the right amounts.

It helps you grow if you are not growing properly and do not have enough of your own growth hormone. It helps your muscles and bones develop to a more normal size. It also helps you grow if you have Turner Syndrome or kidney failure. Turner Syndrome is a chromosomal syndrome – your health care provider will have told you if you have this. If you have kidney failure, it is important to keep taking the other medicines your health care provider has given you.

2. What you need to know before you use GENOTROPIN

Do not use GENOTROPIN:

- If you are hypersensitive (allergic) to somatropin, metacresol or any of the other ingredients in GENOTROPIN (listed in section 6).
- If you are pregnant or breastfeeding
- If you have had cancer, you must finish your other treatment before you use GENOTROPIN. Your health care provider must be quite sure that the cancer has stopped growing.
- GENOTROPIN cannot help you to grow after the “growth plates” in your main bones have closed together (this means that your bones have finished growing). Your health care provider can test when this has happened, usually at the end of your teenage years.

Warnings and precautions

You must tell your health care provider if you or your child:

- was small at birth, as your health care provider may need to perform some tests before GENOTROPIN treatment is started
- are close to the onset of puberty as it is not recommended to start treatment with GENOTROPIN near onset of puberty

- have diabetes, as you or your child may need to change the dose of ~~your~~ diabetic treatment
- suffer from adrenocortical insufficiency (also known as ACTH deficiency)
- are taking any other medicines, especially hormone replacement therapy (e.g. HRT for oestrogen deficiency), as well as thyroid hormone, steroids, anti-seizure medication or ciclosporin
- have ever had problems with growth hormone treatment in the past
- are on a low sodium diet before using it, as GENOTROPIN contains a very small amount of sodium

What medical checks will you need

It is important that a health care provider supervises your treatment and gives you regular medical checks. This may mean you have to have blood tests.

Your health care provider may check:

- That your body keeps a normal amount of sugar in the blood. Tell your health care provider if you start to pass large amounts of urine and are especially thirsty. Also let your doctor know if you often feel tired, hungry and have lost a lot of weight.
- That your body has the right level of thyroid hormones. Let your health care provider know if you start to feel tired, listless or depressed, if you put on weight, are constipated, or if you get a hoarse voice or unusually dry skin and hair. This might mean that your thyroid gland is becoming underactive. You should also tell your health care provider if you start to feel more hungry than usual, eat more but still lose weight, shake or dislike being in hot places and sweat more. This could mean that your thyroid gland is becoming overactive.
- Your eyes during your treatment if you have very bad headaches, eyesight problems or feel, or actually are sick.

Your health care provider will keep a close eye on you during your growth hormone treatment. You may have to have tests if you have ever had cancer or leukaemia in case it comes back.

It is also important to tell your health care provider if you walk with a limp, or if you start to limp during your growth hormone treatment.

Other medicines and GENOTROPIN

Tell your health care provider if you are taking any other medicines, especially hormone replacement therapy, including thyroid hormone, steroids, anti-seizure medication or ciclosporin.

- 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
- any medicine (including insulin) for the treatment of diabetes
- thyroxine (thyroid hormone) for the treatment of thyroid deficiency
- ciclosporin e.g. for the treatment of severe skin disease (psoriasis), rheumatoid arthritis or after transplant surgery
- hormone therapy e.g. Hormone Replacement Therapy for oestrogen deficiency

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.) Please consult your doctor, pharmacist or other health care provider for advice.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

If you are pregnant, you must not be given GENOTROPIN.

Stop using GENOTROPIN if you get pregnant or think you might be pregnant.

Driving and using machines

No effects of GENOTROPIN on the ability to drive and use machines have been observed.

It is not always possible to predict to what extent GENOTROPIN may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which GENOTROPIN affects them.

GENOTROPIN contains mannitol

Mannitol may have a laxative effect.

3. How to use GENOTROPIN

Do not share medicines prescribed for you with any other person.

How much ~~of~~ GENOTROPIN should you use

Your dose depends on your size, the condition for which you are being treated and how well growth hormone works for you. Everyone is different. Always stick to the dose you have been told by your health care provider.

If you are not growing properly and do not have enough of your own growth hormone, your health care provider will work out your dose for your condition.

The usual dose is 0,5 – 0,7 IU per kg body weight per week or approximately 14 – 20 IU per m^2 body surface area per week.

When growth hormone deficiency continues into adolescence, GENOTROPIN should be continued until completion of physical development.

If you have Turner syndrome, the usual dose is 1,0 IU per kg body weight per week or 28 IU per m^2 body surface area per week.

If you have kidney failure, the usual dose is 30 IU per m^2 body surface area per week (approximately 1 IU per kg body weight per week).

The weekly dose is usually divided into six to seven injections. These daily injections are very small, so they are more comfortable. If you forget what your dose should be, speak to your health care provider.

If you are still growing your health care provider will measure you regularly while you are using GENOTROPIN. This is to make sure that you are getting the right amount of growth hormone and that it is working well for you. At your check up, your doctor may change your dose of growth hormone.

How GENOTROPIN is used

These cartridges can be used in a GENOTROPIN Pen injection device.

You should have already been shown how to inject GENOTROPIN under your skin by your health care provider at your clinic. Follow their instructions exactly. If you cannot remember what to do, do not try to do your injection. Ask your health care provider to show you again.

You can take your GENOTROPIN out of the fridge half an hour before your injection. This lets it warm up slightly and can make your injections more comfortable.

When you are mixing your GENOTROPIN, DO NOT shake the solution. Swirl it gently. Shaking the solution could make your growth hormone foam and damage the active ingredient. Check the solution for clarity and only use clear solutions that are particle free.

Remember to wash your hands and clean your skin first.

Inject the GENOTROPIN at about the same time every day. Bedtime is a good time because it is easy to remember. It is also natural to have a higher level of growth hormone at night.

Most people do their own injections into their thigh or their buttock. Do your injection in the place you have been shown by your health care provider or nurse. Use a slightly different place for your injection each time. This gives your skin and the area under your skin time to recover from one injection before it gets another one in the same place.

Remember to put your GENOTROPIN back in the fridge straight after your injection.

How can you throw away your needles and syringes safely

When you have finished with a needle, you must throw it away carefully so that no-one will see it, use it or prick themselves on it.

You can get a special ‘sharps’ bin from your hospital or growth clinic.

Never throw away needles or empty cartridges with your ordinary rubbish.

If you use more GENOTROPIN than you should

Don’t worry if you inject slightly too much GENOTROPIN by mistake. Have your next injection as usual the next day.

If you inject much more than you should, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre as soon as possible. Your blood sugar level could fall too low and later rise too high. You might feel shaky, sweaty, sleepy or 'not yourself', and you might faint.

If you forget to use GENOTROPIN

Have your next injection at the usual time the next day. Do not take an extra dose to make up for the one you have missed.

It is best to use your GENOTROPIN regularly. Keep a note of any missed injections and tell your medical practitioner at your next check-up.

If you stop using GENOTROPIN

There are no withdrawal effects if treatment with GENOTROPIN is stopped.

4. Possible side effects

GENOTROPIN can have side effects.

Not all side effects reported for GENOTROPIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using GENOTROPIN, please consult your doctor, pharmacist or health care provider for advice.

Frequent side effects:

- Temporary reddening, itchiness or pain at the injection site. The skin around the injection area could become uneven or lumpy, but this should not happen if you inject in a different place each time.
- Joint pain

Other side effects:

- leukaemia (blood cancer)
- Type 2 diabetes mellitus
- tingling, pricking or burning sensation of the skin*
- intracranial pressure (which causes symptoms such as strong headache, visual disturbances or vomiting)
- muscle pain*
- stiffness in the arms and legs*
- swelling of the hands, feet and face due to fluid retention*
- rash
- itching (pruritis) alone or with a rash (urticaria)

*These symptoms are generally mild to moderate and may be seen for a short time at the start of treatment, but they disappear spontaneously or when the dosage is lowered.

You may find that injecting GENOTROPIN under your skin can sometimes be a little bit painful. This might be the case if you have just started using GENOTROPIN and it is important to remember that the injections usually become easier with practice. However, if you find that doing your injections is very painful or suddenly becomes very painful, tell your health care provider. Also let them know if your muscles start to feel tender, painful and weak.

You may also have reduced levels of serum cortisol in your body, high levels of lipids and low levels of calcium in your blood. You may also have increased amounts of proteins and red blood cells in your urine.

If you notice these or any other side effects not mentioned in this leaflet while you are using GENOTROPIN tell your health care provider.

Reporting of side effects

If you get 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 to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form",** found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of GENOTROPIN.

5. How to store GENOTROPIN

Store all medicines out of the reach and sight of children.

Do not use any of your GENOTROPIN after the expiry date on the pack. You should make sure to keep the container in the outer carton in order to protect from light. Do not freeze. If it freezes, do not use it.

Before reconstitution (mixing the powder with the liquid) keep your growth hormone in the fridge (between 2 °C and 8 °C). GENOTROPIN can be stored at room temperature (at or below 25 °C) for up to 1 month.

After reconstitution (once you have mixed the powder with the liquid), it is even more important to look after your growth hormone properly. You can use GENOTROPIN for up to 21 days after mixing. Remember to keep it in the fridge away from light and do not let it freeze.

Use a cool box if you are travelling away from home.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Your GENOTROPIN Pen needs no maintenance. Wiping with a damp cloth can clean the exterior. The GENOTROPIN Pen should be stored in its case to protect it from dirt and damage. Refer to the Instructions for Use inside the GENOTROPIN Pen pack for more information.

6. Contents of the pack and other information

What GENOTROPIN contains

GENOTROPIN comes in a cartridge which has two sections. One contains powder and the other contains liquid. The powder section contains the active ingredient called somatropin. Each cartridge contains 5,3 mg of somatropin.

The powder also contains other ingredients, these are:

Disodium phosphate anhydrous

Glycine

Mannitol

Sodium dihydrogen phosphate anhydrous

The liquid section of the cartridge contains:

Mannitol

Water for injections

metacresol (preservative)

When mixed together, the powder and the liquid make 1mL of solution for injection.

What GENOTROPIN looks like and contents of the pack

GENOTROPIN comes in a cartridge with two sections. One section contains a dry, white powder and the other contains a clear liquid.

GENOTROPIN is available in packs of 1 x 1 mL two-compartment cartridge or 5 x 1 mL two-compartment cartridges.

The GENOTROPIN Pen administering device is available separately by contacting the Pfizer Call centre on 0860 PFIZER.

Holder of Certificate of Registration

Pfizer Laboratories (Pty) Ltd

85 Bute Lane

Sandton 2196

South Africa

Tel: +27(0)11 320 6000 / 0860 734 937 (toll free South Africa)

This leaflet was last revised in

20 May 2025

Registration number

X/21.10/214