

GENOTROPIN®

somatropin (rbe), recombinant human growth hormone

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions that you may have about GENOTROPIN.

It does not contain all the available information.

It does not take the place of talking with your doctor, nurse or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using GENOTROPIN against the expected benefits it will have for you.

If you have any concerns about this medicine, ask your doctor, nurse or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What GENOTROPIN is used for

GENOTROPIN is a growth hormone.

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.

Before you use GENOTROPIN

When you must not use GENOTROPIN (discuss with your doctor)

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 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.

Do not use GENOTROPIN if:

- the expiry date printed on the packaging has passed.
- the packaging is torn or shows signs of tampering.

Do not give this medicine to anyone other than the person for whom it has been prescribed.

Before you start to use GENOTROPIN

Before you start to use GENOTROPIN you should tell your doctor if you have or have had:

- diabetes mellitus
- cancer
- a kidney transplant
- thyroid disease
- adrenocortical insufficiency (also known as ACTH deficiency)
- an allergic reaction to meta-Cresol, which is a preservative in the GENOTROPIN mixing fluid.

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription.

In particular, tell your doctor if you are taking:

- any medicine 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
- cyclosporin 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.

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

Tell your doctor if you are breast-feeding or plan to breast-feed. It is not known whether GENOTROPIN passes into breast milk.

Using GENOTROPIN

How to use GENOTROPIN

GENOTROPIN is given by injection under the skin (sub-cutaneous). It is important to use a different site every day to prevent wasting of skin fat at the injection site.

Your doctor, nurse or pharmacist will tell you how many milligrams (mg) of GENOTROPIN you must use and how often.

You will be taught to mix and inject your GENOTROPIN using a re-usable Pfizer reconstitution device (GENOTROPIN Mixer) or administration device (GENOTROPIN Pen), or a disposable pre-filled pen (GENOTROPIN GoQuick®).

It is important to use the correct cartridge with the correct pen. GENOTROPIN pens and cartridges are colour coded to help you match the cartridge to the corresponding pen. You must only use:

- GENOTROPIN Pen 5 (green) with GENOTROPIN 5 mg cartridges (green);
- GENOTROPIN Pen 12 (purple) with GENOTROPIN 12 mg cartridges (purple).

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

It is a good idea to refer to the instruction sheet you receive each time you mix and inject.

It is very important that you use your GENOTROPIN exactly as you have been instructed.

Use your GENOTROPIN 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.

Tell your doctor, nurse or pharmacist if you forget to use your GENOTROPIN. Do not use a double dose to make up for the dose you missed.

Do not stop using your GENOTROPIN without your doctor's permission. Missing injections can reduce effectiveness and you risk being taken off growth hormone altogether.

While you are using GENOTROPIN

Tell your doctor, nurse or pharmacist if you have any concerns while using GENOTROPIN.

Things you must do

Tell your doctor if you become pregnant while you are using GENOTROPIN.

Tell your doctor if you start to have difficulty breathing or start to snore, or have an increase in snoring while you are using GENOTROPIN.

Tell your doctor if you stop or change your oral oestrogen therapy.

Tell your doctor if you stop or change your glucocorticoid therapy.

Inspect the product before use.

Speak to your doctor or pharmacist before use if you have concerns about how the product looks e.g. if it looks different from normal.

After mixing, check to make sure that the powder is completely dissolved and the solution is clear. You can assist the powder to dissolve by using a slow swirling motion. However, do not shake as this may deactivate the growth hormone.

Things you must not do

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.

You must not miss injections regularly.

Do not heat or freeze your mixed or unmixed GENOTROPIN.

Do not give your GENOTROPIN to anyone else.

Use all the GENOTROPIN in each cartridge. Do not discard any unused GENOTROPIN without discussing this with your doctor, nurse or pharmacist.

Do not refill empty GoQuick pens.

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 administration device or pre-filled pen
- broken cartridge

If any of these problems occur contact the person who trained you

on how to mix your GENOTROPIN.

GENOTROPIN has preservative in it. You can store it in a refrigerator for up to 28 days after it has been mixed.

Side Effects

GENOTROPIN, like all medicines, may cause unwanted side effects in some people.

If you experience any of the following you must contact your doctor as soon as possible:

- a reaction at or around the site of injection
- nausea, vomiting, headaches or problems with your vision
- limping
- swelling of the arms or legs
- painful joints or muscle aches and pains
- unusual muscle stiffness
- tingling or numbness in your fingers, hands or feet
- 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
- curvature of the spine
- discomfort or pain in the hip or knee.

Storage and Disposal

Storage

Keep GENOTROPIN in the original packaging during storage.

GENOTROPIN needs protection from light.

Store your GENOTROPIN (mixed or unmixed) in the refrigerator at 2-8°C.

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.

It must not be frozen or heated above 25°C.

Contact your doctor, nurse or pharmacist if you have any questions about storing GENOTROPIN.

Take GENOTROPIN out of the refrigerator approximately 1/2 hour before your injection. This will bring it to room temperature (about 25°C). It is more comfortable to inject at this temperature.

If you are using an administration device or the GoQuick pen always remove the injection needle before storing in the refrigerator. This will prevent leakage of GENOTROPIN through the needle.

Your reconstitution or administration devices come with a special storage box. Always store your device in this container in the refrigerator to protect the device and cartridge from damage.

Disposal

Used needles, syringes and empty GENOTROPIN cartridges and empty GoQuick 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 any unused cartridges or GoQuick pens that you have remaining.

Product Description

What GENOTROPIN looks like

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

GENOTROPIN is mixed with 1 mL of diluent.

GENOTROPIN cartridges come in packs containing either 1 or 5 two-chamber cartridges.

The GENOTROPIN cartridge is mixed using a Pfizer reconstitution device (GENOTROPIN Mixer) or administration device (GENOTROPIN Pen).

GENOTROPIN also comes in a disposable multidose pen (GoQuick) that contains the GENOTROPIN cartridge. The GENOTROPIN in the GoQuick pen is mixed when you start a new pen.

Ingredients

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

GENOTROPIN contains meta-Cresol as preservative.

Other inactive ingredients are glycine, sodium phosphate, mannitol and water.

Identification

GENOTROPIN can be identified by the Australian Register Number:

- GENOTROPIN 5 mg with preservative, AUST R 78811.
- GENOTROPIN 12 mg with preservative, AUST R 96397.
- GENOTROPIN 5 mg GoQuick pre-filled pen with preservative, AUST R 166829.

- GENOTROPIN 12 mg GoQuick pre-filled pen with preservative, AUST R 166831.

Supplier

GENOTROPIN is supplied in Australia by:

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free number: 1800 675 229

www.pfizer.com.au

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