

GENOTROPIN[®]

5.3 mg and 12 mg cartridges

recombinant human somatotropin (rhGH)

What is in this leaflet

This leaflet answers some common questions about GENOTROPIN.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

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

If you have any concerns about using this medicine, ask your doctor 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 promotes the growth of long bones (for example: upper legs) in children with reduced height due to lower than normal levels of growth hormone. It is also used to treat reduced growth in girls with Turner's syndrome and in children prior to the onset of puberty who have long-term

kidney problems causing growth disturbance.

GENOTROPIN is also used in adults who have low levels of growth hormone due to a disease in the pituitary gland or hypothalamus in the brain.

GENOTROPIN is used for children and adults who have a genetic disorder called Prader-Willi syndrome (symptoms include intellectual impairment, uncontrollable urge to eat).

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 therapy

- have Prader-Willi syndrome and are severely overweight or have breathing difficulties
- are allergic to any of the ingredients of GENOTROPIN.

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
- 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

- corticosteroids such as cortisol or dexamethasone e.g. for the treatment of severe asthma, some skin conditions, rheumatoid arthritis or adrenal insufficiency
- epilepsy medicines e.g. carbamazepine
- cyclosporin e.g. for the treatment of severe skin disease (psoriasis), rheumatoid arthritis or after transplant.
- hormone therapy e.g. HRT for oestrogen deficiency, menopause or osteoporosis, 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 breastfeeding 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 of GENOTROPIN you must use each day.

You will be taught to mix and inject your GENOTROPIN

using an 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 5.3 (blue) with GENOTROPIN 5.3 mg cartridges (blue);

GENOTROPIN Pen 12 (purple) with GENOTROPIN 12 mg cartridges (purple).

The GENOTROPIN 5.3 mg *GoQuick* pen is colour coded blue. 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.

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 talking to your doctor. Missing injections can slow your growth 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.

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 help 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 fill empty *GoQuick* pens.

Things to be careful of

The instructions for mixing the GENOTROPIN cartridge 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.

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
- swelling of the face
- painful joints or muscle aches and pains
- unusual muscle stiffness
- tingling or numbness in your 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.

- discomfort or pain in the hip or knee.

If you use too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (telephone 0800 POISON or 0800 764 766) for advice, if you think that you or anyone else may have used too much GENOTROPIN. Do this even if there are no signs of discomfort or poisoning.

After using GENOTROPIN

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 ½ 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 the 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 administration device comes 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's 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 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 comes in two strengths - 5.3mg and 12 mg. Both strengths are mixed in 1 mL of diluent.

The GENOTROPIN cartridge is mixed using the 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 (recombinant human growth hormone, or biosynthetic human growth hormone). It is a man-made substance which is produced in a laboratory.

GENOTROPIN 5.3 mg and 12 mg also contain meta-cresol as preservative. Other inactive ingredients are glycine, sodium phosphate, mannitol and water.

Supplier

GENOTROPIN is supplied in New Zealand by:

Pfizer New Zealand Limited
PO Box 3998
Auckland
New Zealand

Toll Free number: 0800 736 363

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