

GENOTROPIN MiniQuick®

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 MiniQuick.

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 MiniQuick 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 MiniQuick is used for

GENOTROPIN is a growth hormone. GENOTROPIN MiniQuick is a device containing a single dose of GENOTROPIN for injection.

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 MiniQuick for another purpose. Ask your doctor if you have any questions about why GENOTROPIN MiniQuick has been prescribed for you.

Before you use GENOTROPIN MiniQuick

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

Your doctor will not prescribe GENOTROPIN MiniQuick 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 MiniQuick 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 MiniQuick

Before you start to use GENOTROPIN MiniQuick 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).

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
- other 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 MiniQuick

How to use GENOTROPIN MiniQuick

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

GENOTROPIN MiniQuick is available in 8 different strengths. Your doctor, nurse or pharmacist will decide which MiniQuick you should use depending on your weight.

You will be taught to prepare and inject your GENOTROPIN MiniQuick. It is a good idea to refer to the Directions For Use at the back

of this leaflet each time you prepare and inject.

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

Use your GENOTROPIN MiniQuick 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 MiniQuick. Do not use a double dose to make up for the dose you missed.

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

While you are using GENOTROPIN MiniQuick

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

Things you must do

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

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.

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 the

MiniQuick as this may deactivate the growth hormone.

Use GENOTROPIN MiniQuick as soon as possible after mixing.

After mixing, GENOTROPIN MiniQuick can only be stored in a refrigerator for up to 24 hours.

Things you must not do

GENOTROPIN MiniQuick 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 MiniQuick.

Do not give your GENOTROPIN MiniQuick to anyone else.

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

Things to be careful of

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

- loss of GENOTROPIN activity
- broken or jammed MiniQuick device
- broken cartridge.

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

Side Effects

GENOTROPIN MiniQuick, 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 MiniQuick in the original packaging during storage.

GENOTROPIN MiniQuick needs protection from light.

Store your GENOTROPIN MiniQuick in the refrigerator at 2-8°C.

If it is stored in the refrigerator GENOTROPIN MiniQuick can be used at any time before the expiry date on the labels.

You can store GENOTROPIN MiniQuick outside the refrigerator for 6 months provided:

- the powder has not been mixed with the solution
- the temperature remains below 25°C
- it is not put back in the refrigerator
- it is disposed of safely if it is not used (see below).

GENOTROPIN MiniQuick must not be frozen or heated above 25°C.

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

If stored in the refrigerator, take the GENOTROPIN MiniQuick out of the refrigerator approximately half an hour before your injection. This will bring it to room temperature (about 25°C). It is more comfortable to inject at this temperature.

Disposal

Used needles and the empty GENOTROPIN MiniQuick 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 MiniQuick inform your doctor, nurse or pharmacist of the number of any unused MiniQuicks you have remaining.

Product Description

What GENOTROPIN MiniQuick looks like

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

GENOTROPIN MiniQuick comes in nine strengths. The volume of the injection is 0.25 millilitres (mL) for all strengths.

Each pack contains seven MiniQuicks of the particular strength prescribed for you.

Ingredients

The active ingredient in GENOTROPIN MiniQuick is

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

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

GENOTROPIN MiniQuick does not contain any preservatives.

Identification

GENOTROPIN MiniQuick can be identified by the Australian Register Number:

- 0.4 mg: AUST R 76617
- 0.6 mg: AUST R 76616
- 0.8 mg: AUST R 76615
- 1.0 mg: AUST R 76614
- 1.2 mg: AUST R 76613
- 1.4 mg: AUST R 76612
- 1.6 mg: AUST R 76611
- 1.8 mg: AUST R 76610
- 2.0 mg: AUST R 76608

Supplier

GENOTROPIN MiniQuick is supplied in Australia by:

Pfizer Australia Pty Ltd
 ABN 50 008 422 348
 38-42 Wharf Road
 West Ryde NSW 2114
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Toll Free number: 1800 675 229

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