HUMATROPE®

Somatropin (rbe)

Consumer Medicine Information

What is in this leaflet

This leaflet is designed to provide you with answers to some common questions about this medicine. It does not contain all the available information and does not take the place of talking with your doctor.

The information in this leaflet was last updated on the date shown on the final page. More recent information on this medicine may be available. Make sure you speak to your pharmacist, nurse or doctor to obtain the most up to date information on this medicine. You can also download the most up to date leaflet from www.lilly.com.au. The updated leaflet may contain important information about HUMATROPE and its use that you should be aware of.

All medicines have risks and benefits. Your doctor has more information about this medicine than is contained in this leaflet. Also, your doctor has had the benefit of taking a full and detailed history from you and is in the best position to make an expert judgement to meet your individual needs.

If you have any concerns about using this medicine, talk to your doctor or health care professional.

Keep this leaflet with this medicine.

You may need to read it again.

What HUMATROPE is used for

HUMATROPE is a biosynthetic human growth hormone. It is used in children who do not produce enough natural growth hormone, in girls who have Turner syndrome, in children with chronic renal insufficiency, and children born small for gestational age. HUMATROPE helps these children to grow at a natural rate.

HUMATROPE is also used in adults who do not produce enough natural growth hormone. In adults, HUMATROPE helps to decrease body fat, in growth hormone deficient adults only.

Your doctor may have prescribed HUMATROPE for another reason.

Ask your doctor if you have any questions about why HUMATROPE has been prescribed for you.

Before using HUMATROPE

A doctor who is experienced in the diagnosis and management of patients who do not produce enough natural growth hormone should direct your treatment with HUMATROPE.

Tell your doctor if you have any of the following conditions or if you have ever experienced any of these conditions.

When you must not use HUMATROPE

You must not use HUMATROPE if you have an active tumour (cancer).

However, your doctor may prescribe HUMATROPE if you have had a brain tumour and need no further treatment for it. You should be re-examined frequently to make sure that the tumour does not return.

You must not use HUMATROPE cartridges if you are allergic to meta-Cresol or glycerol.

Signs of an allergic reaction may include skin rash, itching, shortness of breath or swelling of the face, lips or tongue.

HUMATROPE should not be used for growth promotion in children if their bones have finished growing (closed epiphyses).

You must not use HUMATROPE if you have a dangerous and severe illness due to complications from open heart surgery or stomach surgery, multiple accidental trauma or if you have severe breathing failure.

HUMATROPE should not be used if you have diabetic retinopathy (diabetic eye disease).

You must not use HUMATROPE if the packaging is torn, or the cartridges show signs of tampering.

You must not use HUMATROPE after the expiry date printed on the pack.

If you are not sure whether you should start using HUMATROPE, talk to your doctor or health care professional.

Before you use HUMATROPE

Tell your doctor if you have allergies to:

- any other medicines
- any other substances such as foods, preservatives or dyes.

Tell your doctor if you are a diabetic or require insulin treatment.

More or less insulin may be needed when using HUMATROPE.

Tell your doctor if you suffer headaches and blurred vision.

Tell your doctor if you have lower than normal levels of adrenocorticotropic hormone (ACTH).

Less glucocorticoid therapy may be needed when using HUMATROPE.

Tell your doctor if you have had a brain tumour.

You should be examined frequently to make sure that the tumour does not return.

Tell your doctor if you intend to have or have had a kidney transplant.

You should stop using HUMATROPE at the time of kidney transplantation.

Treatment with HUMATROPE in children with chronic renal insufficiency should be started only after growth disturbance has been confirmed over a period of at least one year.

Tell your doctor if you have Prader-Willi Syndrome

(a condition in children with symptoms of floppiness, obesity, small hands and feet and mental retardation).

Tell your doctor if you have scoliosis

(curvature of the spine that can develop during periods of rapid growth).

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 HUMATROPE passes into breast milk.

Tell your doctor about these things before you use HUMATROPE.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you have bought without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may be affected by HUMATROPE or may affect how it works. These include:

- cortisone medicines (such as prednisone and anti-asthma inhalers like Becotide®). Combining cortisone medicines with HUMATROPE may reduce the effect of HUMATROPE.
- orally taken estrogen
- sex steroids, cyclosporine and some anticonvulsants

These medicines may be affected by HUMATROPE, or may affect how well it works. You may need to use different amounts of your medicine, or you may need to use different medicines. Your doctor will advise you.

Your doctor or health care professional may have more information on medicines to be careful with or to avoid while using HUMATROPE.

How to use HUMATROPE

Carefully follow all directions given to you by your doctor or health care professional. These may differ from the information contained in this leaflet.

HUMATROPE is given by injection under the skin (subcutaneous) or into a muscle (intramuscular).

It is important to use a different injection site every day.

Repeated injections into the same site can cause wasting of fat under the skin or a hardened bump in the skin.

You will be taught to mix and inject HUMATROPE using the HUMATROPE injection device. It is a good idea to refer to the instruction sheet each time you mix and inject HUMATROPE.

How much to use

Your doctor or health care professional will tell you how much HUMATROPE you must use each week.

To gain the best result, it is very important to use HUMATROPE exactly as instructed.

If possible, give the injection in the evening.

Normally, the body makes growth hormone at night. Giving the injection at night helps to copy this process.

How long do I use it

Do not stop using HUMATROPE without checking with your doctor.

If you forget to inject it

If you forget to inject HUMATROPE, talk with your doctor or nurse.

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

If you inject too much (Overdose)

If you think that you or anyone else has injected too much HUMATROPE, immediately telephone your doctor or the Poisons Information Centre (13 11 26), or go to Accident and Emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

If you inject too much HUMATROPE, you may experience sweating, confusion, vomiting, hunger, faintness and dizziness which are all associated with low blood sugar levels.

While you are using HUMATROPE

Things you must do

Tell all doctors and health care professionals who are treating you that you are using HUMATROPE.

If you are about to be started on any new medicine, tell your doctor or health care professional that you are using HUMATROPE.

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

Change the site of injection every day.

Standard treatment for kidney failure should be continued during treatment with HUMATROPE in children with chronic renal insufficiency.

Things you must not do

Do not give HUMATROPE to anyone else, even if their symptoms seem similar to yours or they have the same condition as you.

Your doctor has prescribed HUMATROPE for you and for your condition.

Do not stop using HUMATROPE without checking with your doctor.

Side effects

Tell your doctor or health care professional as soon as possible if you do not feel well while using HUMATROPE.

Like other medicines, HUMATROPE may cause some unwanted side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you experience some of these side effects.

Ask your doctor or health care professional to answer any questions you may have.

Tell your doctor if you notice any of the following side effects and they worry you:

- mild, temporary swelling
- skin reactions at the site of injection
- pain at the site of injection
- headache
- weakness
- localised muscle pain
- swelling of the hands, ankles or feet
- back pain, uneven shoulder height or uneven leg length
- earache
- tiredness, lethargy, muscle weakness, cramps, feeling the cold, a slow heart rate, dry and flaky skin, hair loss, a deep and husky voice and weight gain (hypothyroidism)
- tingling or numbness of the hands or feet
- carpal tunnel syndrome
- difficulty breathing
- insomnia (trouble falling asleep or staying asleep)
- in men, an increase in the size of breast tissue

Symptoms of high blood sugar levels such as:

- passing large amounts of urine
- excessive thirst
- dry mouth and skin.

Tell your doctor immediately if you notice any of the following:

- a limp while walking
- severe or recurrent headache, problems with your eyesight, feeling sick and/or vomiting
- tiredness, fever, dizziness, looking pale and bone and joint pain.

These side effects are serious and may need urgent medical attention.

Other side effects not listed above may occur in some patients.

Tell your doctor or health care professional if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Tell your doctor if you notice anything unusual or if you are concerned about any aspect of your health, even if you think the problems are not connected with this medicine and are not referred to in this leaflet.

After injecting HUMATROPE

Storage

HUMATROPE cartridges and diluent must not be FROZEN or HEATED above room temperature (25°C) at any time.

Store HUMATROPE cartridges and diluent in the refrigerator (2°C to 8°C). They must not be FROZEN.

After the contents of the HUMATROPE cartridge have been mixed with the diluent, it must be stored in a refrigerator at 2°C to 8°C. DO NOT FREEZE.

If any reconstituted product in the HUMATROPE cartridge remains after 28 days, it should be discarded.

Do not keep the mixed HUMATROPE in plastic syringes.

All medicines should be kept where young children cannot reach them.

There will be an expiry date (month, year) on your HUMATROPE container.

The medicine should not be used after this date because it may have lost some of its strength.

Disposal

Empty HUMATROPE cartridges and any needles and syringes should be disposed of in a 'sharps' container or

similar puncture proof container composed of hard plastic or glass.

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

When you are approved for HUMATROPE treatment, your supply of cartridges will be sent every three months.

Inform your doctor or nurse of the number of unused cartridges you have remaining when you are due for this new supply.

Do not throw away any unused cartridges.

Product Description

What it looks like

HUMATROPE is a powder and is available in the following strengths:

- Cartridges of 6 mg (18 IU) with a 3.17 mL diluent syringe. When reconstituted with the diluent provided the cartridge contains Somatropin 2.07 mg/mL.
- Cartridges of 12 mg (36 IU) with a 3.15 mL diluent syringe. When reconstituted with the diluent provided the cartridge contains Somatropin 4.17 mg/mL.
- Cartridges of 24 mg (72 IU) with a 3.15 mL diluent syringe. When reconstituted with the diluent provided the cartridge contains Somatropin 8.46 mg/mL.

Ingredients

The active ingredient in HUMATROPE is somatropin (rbe or recombinant growth hormone). It is produced in a laboratory.

Inactive ingredients:

- mannitol
- glycine
- sodium phosphate dibasic
- phosphoric acid and/or sodium hydroxide.

The diluent contains:

- meta-cresol
- glycerol
- water for injections.

Supplier

HUMATROPE is a product of:

Eli Lilly Australia Pty Ltd

Level 9, 60 Margaret Street

Sydney NSW 2000

Australian Registration Numbers:

HUMATROPE 6 mg (18 I.U.) -

AUST R 53423

HUMATROPE 12 mg (36 I.U.) -

AUST R 53365.

HUMATROPE 24 mg (72 I.U.) -

AUST R 53364

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