

ZOMACTON®

Powder and solvent for solution for injection

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 ZOMACTON.

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 your child using ZOMACTON against the expected benefits it will have for your child.

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 ZOMACTON is used for

ZOMACTON is a growth hormone. The active ingredient is somatropin.

ZOMACTON is used for the long-term treatment of children who have growth failure due to a low secretion of natural human growth hormone. ZOMACTON acts the same way as growth hormone naturally produced by the body increasing the height and size of body organs. The product as supplied is intended for your child's use only. It should not be used in adults.

Ask your doctor if you have any questions about why this medicine has been prescribed.

Your doctor may have prescribed ZOMACTON for another purpose.

This medicine is only available with a doctor's prescription.

This medicine is not expected to affect the ability to drive a car or operate machinery or your child's ability to ride a bike or climb trees.

Before you use ZOMACTON

ZOMACTON should only be used under the supervision of a doctor experienced in the treatment of growth hormone deficiency.

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

Your doctor will not prescribe ZOMACTON if your child:

- has an allergy to any of the ingredients listed at the end of this leaflet
- has closed epiphyses (this means that your bones have finished growing)
- has an active tumour or evidence of cancer growth
- is currently being treated for cancer
- has a serious injury or illness, or surgical procedure, requiring intensive care
- has severe kidney disease and requires kidney transplantation.

This medicine is not to be used in females of childbearing potential.

The effects of the medicine during pregnancy and in females of childbearing potential have not been investigated.

Do not use ZOMACTON if:

- the expiry date (EXP) 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 ZOMACTON

Before your child starts to use ZOMACTON you should tell your doctor if your child has or has ever had:

- previous cancerous growth
- inflammation of the pancreas (severe upper stomach pain, often with nausea and vomiting)
- diabetes mellitus (sugar diabetes)
- glucose intolerance
- thyroid disease
- active cancer including brain cancer
- high blood pressure in the head
- a limp, or hip or knee pain (caused by slipped capital femoral epiphysis, SCFE)
- Prader-Willi syndrome - a genetic condition characterised by learning difficulties, growth abnormalities, and obsessive eating
- Leukaemia (increased number of white blood cells)

- Scoliosis, a condition characterised by curvature of the spine
- an allergic reaction to foods, dyes, preservatives or any other medicines
- an allergic reaction to any of the ingredients listed at the end of this leaflet.

Tell your doctor if your child is breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before your child starts using ZOMACTON.

Using ZOMACTON

How to use ZOMACTON

ZOMACTON is injected under the skin (sub-cutaneous) by use of a needle or the ZOMAJET needle-free administration device, which is supplied separately. 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 ZOMACTON your child must use each day.

It is very important that your child uses ZOMACTON exactly as instructed.

ZOMACTON should be used 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.

Allow the product to warm to room temperature before injecting and check for cloudiness. If cloudy do not use.

Tell your doctor, nurse or pharmacist if your child forgets to use ZOMACTON. Do not use a double dose to make up for the dose that has been missed.

Do not stop using ZOMACTON without your doctor's permission.

Missing injections can reduce effectiveness and you risk being taken off growth hormone altogether.

Preparation

The growth hormone is supplied in a powder form that must be prepared for injection by mixing it with a diluent (a liquid in which it can be mixed for injection) before use. For ZOMACTON 10 mg, use the entire contents of the pre-filled solvent syringe to reconstitute the powder for injection.

Once you have reconstituted the growth hormone with the diluent, it is ready for injection. Each reconstituted vial contains a preservative and enough medication for several doses.

You will be taught to mix and inject ZOMACTON using needles or the ZOMAJET needle-free administration device. It is a good idea to refer to the instruction sheet you receive each time you mix and inject.

The ZOMAJET Vision X is for use with ZOMACTON 10 mg. Each device is supplied with 3 heads in different sizes that are labelled A, B and C. Detailed instructions for choosing the correct head, selfinjecting and evaluating your injection technique come with the ZOMAJET needle free device. If you experience problems using the ZOMAJET device, contact your nurse or physician.

While you are using ZOMACTON

Tell your doctor, nurse or pharmacist if you have any concerns while your child is using ZOMACTON.

Things you must do

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

ZOMACTON should be used strictly according to the instructions you have been given. Do not change the dose unless your doctor has told you to.

You must not miss injections regularly.

Do not heat or freeze your mixed or unmixed ZOMACTON.

Do not give your ZOMACTON to anyone else.

Things to be careful of

The instructions for mixing the ZOMACTON powder must be followed exactly otherwise problems such as the following may occur:

- loss of ZOMACTON activity
- broken or jammed administration device.

If any of these problems occur contact the person who trained you on how to mix your ZOMACTON.

Taking other medicines

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 or rheumatoid arthritis

- epilepsy medicines, e.g. carbamazepine, ethosuximide or tiagabine
- cyclosporine e.g. for the treatment of severe skin disease (psoriasis), rheumatoid arthritis or after transplant surgery.

Side Effects

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

Do not be alarmed by the following list of side effects. Your child may not experience any of them.

Ask your doctor or pharmacist to answer any questions that you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- pain at the injection site
- injection site bruising or bleeding and an underactive thyroid gland, causing a decrease in metabolism (e.g. tiredness, lethargy, muscle weakness, cramps, feeling the cold, a low heart rate, dry and flaky skin, hair loss, a deep and husky voice, weight gain)
- build-up of fluid in the body and/ or swelling of hands ankles or feet
- unusual weakness
- joint pain
- aching muscles, muscle tenderness or weakness, not caused by exercise
- headache
- unusual muscle stiffness causing poor control of movement.

The above list includes the more common side effects of your medicine (affecting between 1 in 10 and 1 in 100 patients).

Tell your doctor as soon as possible if you notice any of the following:

- tiredness, headaches, being short of breath when exercising, dizziness and looking pale
- fast heart beat
- dizziness
- swelling under the eyes
- unusual changes in vision or double vision
- vomiting
- abdominal pain
- excessive gas in the stomach or bowel
- nausea
- general weakness
- bleeding, shrinkage or wastage at the injection site or elsewhere
- low blood sugar
- high phosphate levels in the blood
- bone pain
- numbness, tingling, or burning sensations in the thumb and fingers
- stiffness in the extremities
- a new abnormal growth in any part of the body
- sleepiness
- rapid, uncontrollable movements of the eyes
- loss of control of the bladder
- blood in urine
- passing more urine than normal
- mood swings
- genital discharge
- excessive hairiness.

The above list includes serious side effects which may require medical attention. Serious side effects are usually rare or very rare (affecting less than 1 in 1,000 patients).

If you notice any of the following, tell your doctor immediately or go to the Accident and Emergency at your nearest hospital:

- wheezing, swelling of the lips/ mouth, difficulty in breathing, hay fever, lumpy rash (hives) or fainting. These could be a symptom of an allergic reaction
- hip pain or limp. If your child develops hip pain or limp contact your doctor

- high blood pressure
- diarrhea
- kidney problems
- diabetes mellitus type II (sugar diabetes)
- numbness or weakness of the arms and legs
- tingling or numbness
- high blood pressure in the brain
- inability/trouble sleeping
- leukaemia
- swollen breast tissue/breast enlargement in males.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. Very serious side effects are usually rare or very rare (affecting between 1 in 1,000 and 1 in 10,000 patients).

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known. It is important that you tell your doctor about anything unusual, even if it is not mentioned on the list.

Storage

Store your ZOMACTON (mixed or unmixed) in the refrigerator at 2-8°C. It must not be frozen or heated above 25°C. Protect from light.

After making up, the ZOMACTON 10 mg solution is stable for 28 days if in the refrigerator. Discard any remaining solution after this time.

Take ZOMACTON 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.

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

Product Description

What ZOMACTON looks like

The ZOMACTON 10 mg pack contains three components:

- a) a vial containing a white powder (which contains growth hormone)
- b) a pre-filled syringe containing a solution (diluent) for reconstitution of the white powder
- c) an adapter for connecting the prefilled syringe to the vial before reconstitution.

Ingredients

ZOMACTON 10 mg contains the active ingredient somatropin. It also contains mannitol. The diluent contains metacresol and water.

Sponsor

ZOMACTON is supplied by:

Ferring Pharmaceuticals Pty Ltd
Suite 2, Level 1, Building 1,
20 Bridge Street,
Pymble NSW 2073, Australia.

AUST R 156226 - ZOMACTON
somatropin 10 mg multidose
powder for injection vial with
diluent syringe

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