

ZOMACTON(R)

somatropin

CONSUMER MEDICINE INFORMATION

What is in this leaflet?

Please read this information carefully. This leaflet does not contain all the information about ZOMACTON(R). If you have further questions or are not sure about anything, ask your doctor or pharmacist.

What is ZOMACTON(R) used for?

ZOMACTON(R) is used for the long-term treatment of children who have growth failure due to a low secretion of natural human growth hormone. ZOMACTON(R) 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.

Before you use ZOMACTON(R)

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

Do not use ZOMACTON(R) if

- * Your child has ever had an allergic reaction to somatropin, benzyl alcohol or any of the ingredients listed toward the end of this leaflet. (See "Ingredients") -

- * Your child has closed bone growth.
- * Your child has lesions in the brain.
- * The expiry date (EXP) printed on the pack has passed.
- * The packaging is torn or shows signs of tampering.

Tell your doctor if your child:

- * is allergic to foods, dyes, preservatives or any other medicines.
- * is diabetic. They should be checked during treatment for glucose levels that may change during use of ZOMACTON(R). If blood glucose is altered it may require a change in the time of a dose of the injection. Diabetic patients may need to have their insulin dose adjusted.
- * has any thyroid problems. Periodic thyroid tests will be required.
- * is receiving steroids or other hormone treatment or they are taking any other medicines, including medicines you buy without a prescription.

How to use ZOMACTON(R)?

Your doctor will determine the dose that is needed. Make a note of this dose and keep it handy.

Do not use ZOMACTON(R) if the containers are damaged or show signs of tampering, or if the product does not look quite right. Each vial

is intended for use by a single individual patient.

Each reconstituted vial may contain enough medication for several doses so do not discard the vial unless it is completely empty or 14 days after reconstitution. Allow the product to warm to room temperature and check again for cloudiness. If cloudy do not use.

Store the reconstituted vial in the refrigerator between 2 degrees and 8 degrees C. Do not freeze. The reconstituted solution may be used up to 14 days and the vial should be discarded after this time.

If the reconstituted vial is cloudy or particles can be seen, do not use it.

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) prior to use. Once you have reconstituted the growth hormone with the diluent supplied, it is ready for injection. Each reconstituted vial contains a preservative and enough medication for several doses so do not discard the vial until it is completely empty or 14 days after reconstitution.

Before preparing the medication, be sure to wash your hands thoroughly with soap and water. This will prevent infection.

1. Remove the hard plastic top of the diluent vial. Cleanse the top of the diluent vial with an alcohol swab. Remove the needle cap from the syringe and insert the needle into the centre of the

- rubber stopper on the diluent vial.
2. Tilting the vial to one side, slowly and carefully withdraw the diluent by gently pulling back on the plunger of the syringe. Your doctor will advise what volume of diluent to use. Once the syringe is correctly filled with the diluent, withdraw the syringe and needle from the vial and recap the needle slowly and carefully to avoid injury.
 3. Remove the hard plastic top of the growth hormone vial. Cleanse the top of the growth hormone vial with an alcohol swab. Remove the needle cap from the syringe filled with the diluent and insert the needle into the centre of the rubber stopper on the growth hormone vial.
 4. Point the needle towards the side of the vial and slowly push the plunger so that the diluent squirts on to the side of the vial, not directly onto the powder. When all the diluent is in the growth hormone vial, remove the needle from the vial, recap the needle and discard the syringe.
 5. To mix the growth hormone, hold the vial between your hands and gently roll it until the mixture is clear. **NEVER SHAKE THE VIAL!** Sometimes the vial may need to sit a few seconds before the mixture becomes clear. Do not use the vial if the mixture remains cloudy or you see particles floating in the mixture. If air bubbles appear, let the growth hormone sit for a while until they disappear. Use the reconstituted solution as soon as possible and do not store in the syringe.
 6. Write the date you reconstitute the growth hormone on the vial label. It must be used within 14 days. Store reconstituted growth hormone along with all unopened vials of growth hormone in a safe, clean place in the refrigerator.

Injection

To prepare to give an injection of growth hormone, begin by thoroughly washing your hands with soap and water. Check that the vial of growth hormone you are using is clear and that the date of reconstitution is within 14 days.

1. Choose a site for the injection and clean the injection site with an alcohol swab. Using a circular pattern, work from the injection site outward about 5 cm. Allow the alcohol to dry before giving the injection.
2. Cleanse the top of the vial of the reconstituted solution with an alcohol swab. Remove the needle cap from the syringe and insert the needle into the centre of the rubber stopper on the vial. Tilting the vial to one side, slowly and carefully withdraw the required dose by gently pulling back on the plunger of the syringe. Your doctor will work out the dose that is needed.
3. Check that the correct dose is in the syringe. Hold the syringe the way you hold a pencil. With your free hand, pinch the cleansed skin between your fingers and quickly insert the needle into the skin at 45 - 90 degrees with a quick firm wrist motion.
4. Holding the syringe in place, pull back a little on the plunger and check to see if any blood flows into the syringe (vessel check). If you see blood in the syringe, remove the needle and syringe and discard. You will then need to prepare a new syringe for injection.
5. If, during the vessel check, you do not see blood then slowly push down the plunger until the syringe is completely empty.
6. Quickly remove the needle from the skin and apply pressure to the injection site with a dry and sterile gauze pad or a cotton ball. A drop of blood may appear. Apply a small bandage if desired.

7. Dispose of the needle and syringe in a proper container identified by your doctor or pharmacist.
Never dispose of needles and syringes in your household trash.

Injection Sites

There are different injection sites. These are shown by the shading in the diagram in the leaflet supplied with the product. Use a different site each time.

While you are using ZOMACTON(R)

If you notice any of the following signs, contact your doctor:

- * A lump, bruise or redness at the injection site that does not go away.
- * Any sign of infection at the injection site (pus, redness, heat or persistent pain).
- * Severe sharp pain or persistent ache at an injection site.
- * Rash at injection site.
- * If your child develops a limp or hip or knee pain.

What are the side effects?

Check with your doctor as soon as possible if you think your child is experiencing any side effects or allergic reactions due to using ZOMACTON(R), even if the problem is not listed below.

Like other medicines, ZOMACTON(R) can cause some side effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

The most commonly reported side-effects are:

- * Headache
- * Pain at the injection site
- * Injection site bruising or bleeding
- * Swelling or fluid accumulation

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

- * **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.**

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.

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

What to do if you use too much? (Overdose)

The recommended doses should not be exceeded.

Immediately telephone your doctor or Poisons Information Centre (telephone 131126) for advice, if you think you or anyone else may have used too much ZOMACTON(R), even if there are no signs of discomfort or poisoning.

If you are not sure what to do, contact your doctor or pharmacist.

How do I store ZOMACTON(R)?

ZOMACTON(R) powder and diluent should be stored in a refrigerator between 2 degrees and 8 degrees C. Do not freeze. After making up, the solution is stable for 14 days in the refrigerator. Discard any remaining solution after this time.

Please protect the solution from light.

ZOMACTON(R) 1.3 mg AUST R 79589

ZOMACTON(R) 4 mg AUST R 79590

Product description

What ZOMACTON(R) looks like

The ZOMACTON(R) pack contains two components:

- (a) A vial containing a white powder (which contains growth hormone).
- (b) A vial containing a solution (diluent) for reconstitution of the white powder.

Ingredients

ZOMACTON(R) contains the active ingredient somatropin.

ZOMACTON(R) also contains mannitol. The diluent contains sodium chloride, benzyl alcohol and water.

Supplier

ZOMACTON(R) is supplied by:

Ferring Pharmaceuticals Pty Ltd
Suite 2B, Level 2, 802 Pacific
Highway, Gordon NSW 2072

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your child's condition.

This leaflet was prepared in September 2007

The information provided applies only to: ZOMACTON(R).
ZOMACTON(R) is a trademark of Ferring Pharmaceuticals