1. WHAT ZOMACTON IS AND WHAT IT IS USED FOR

ZOMACTON contains the active substance somatropin, also known as growth hormone. Growth hormone is produced naturally in the body. It has an important role in growth. ZOMACTON contains somatropin made in a pharmacetical manufacturing factory.

ZOMACTON is used for the long-term treatment of:
- Growth problems due to a lack of growth hormone in children.
- Growth problems due to Turner’s syndrome (a genetic disorder affecting females).

2. BEFORE YOU USE ZOMACTON

Do not use ZOMACTON
- In children where the bone growth is completed (closed epiphyses).
- If you are on treatment with steroids due to insufficient production of ACTH (adrenocorticotrophic hormone). This is because the dose of steroids will normally need to be adjusted while you are on treatment with ZOMACTON.
- If you are allergic to any of the ingredients of ZOMACTON.
- If you are suffering from complications following open heart or abdominal surgery, multiple injuries from an accident, or respiratory failure.
- In children with chronic renal disease at time for renal transplantation.

Special care with ZOMACTON

ZOMACTON therapy should be used only under the supervision of a qualified physician experienced in the management of patients with growth problems.

- ZOMACTON contains a preservative called metacresol. In very rare cases the presence of metacresol may cause inflammation (swelling) in muscles. If you experience muscle pain or pain at the injection site, inform your doctor.
- Patients with Prader-Willi syndrome should not be treated with ZOMACTON unless they are also suffering from growth hormone failure.
- If you have a family history of diabetes mellitus, your blood sugar levels may be checked at intervals by your doctor.
- If you are diabetic, you will require strict monitoring of blood glucose and your dose may need to be adjusted during treatment. Your doctor will tell you if this is necessary.
- If your growth hormone deficiency is caused by a problem in your brain (intracranial lesion), you will be carefully monitored for worsening or recurrence of the problem. If this is confirmed, the doctor will tell you if you need to stop treatment with ZOMACTON.
- If you have had serious illnesses, such as cancer, treatment with ZOMACTON may make the illness return or get worse. Therefore if you notice any symptoms that worry you, you should tell your doctor immediately.
- Treatment with ZOMACTON may lead to low levels of thyroid hormone that may also need to be treated. To check for this, your doctor will normally carry out tests to ensure that your thyroid gland is working properly.
- Some children with growth hormone deficiency have developed leukemia (increased number of white blood cells), whether or not they have received treatment with growth hormone. However there is no evidence that leukemia/incidence is increased in growth hormone recipients without predisposing factors. No cause and effect relationship with growth hormone treatment has been proven.
- If you are suffering from complications following surgery, trauma or acute respiratory failure.
- If you require surgery, you are seriously injured in an accident or become seriously ill, your doctor may review your treatment.

3. HOW TO USE ZOMACTON

Always use ZOMACTON exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor or nurse will help you decide the best way for you to receive ZOMACTON. They will also tell you the correct dose for you. The dose is given by an injection subcutaneously (under the skin) with a syringe or with the needle-free device, ZOMAJET Vision X.

Dosage

Growth hormone deficiency in children:

- Your doctor will calculate the precise dose for you, based on your bodyweight in kilograms (kg). Generally, a dose of 0.17 - 0.23 mg per kg bodyweight per week is recommended. This weekly amount may be divided into six or seven doses, which means receiving a daily dose of 0.025 - 0.035 mg per kg bodyweight.
- The maximum recommended weekly dosage is 0.33 mg per kg bodyweight. The maximum recommended weekly dosage is 0.37 mg per kg bodyweight which means receiving a daily dose of 0.05 mg per kg bodyweight.
- Tumours Syndrome (female only): Your doctor will calculate the precise dose for you, based on your bodyweight. Generally, a dose of 0.35 mg per kg bodyweight is recommended. This weekly amount may be divided into six or seven doses, which means receiving a daily dose of 0.05 mg per kg bodyweight.

Instructions for reconstitution

ZOMACTON is provided as a powder and should only be mixed with the solvent (liquid) provided.

The 10 mg/ml solution for injection is prepared by mixing the Zomacton powder with 1 ml of solvent using a glass syringe as described below. The steps are presented with a vial adaptor for use with the needle-free device ZOMAJET Vision X and a solvent transfer connector for use for needle injections.

Step 1: Remove the yellow cap from the Zomacton vial.

Step 2: Place the vial adaptor over the centre of the vial with the spike facing downwards. Push down firmly until it clicks into place.

Step 3 & 4: Remove the grey syringe cap and also remove the white vial adaptor cap.

Step 5: Place the vial on a flat surface and hold the vial adaptor. Place the syringe into the vial and push down firmly.

Step 6: Press the syringe plunger slowly. Ensure that all the solution goes into the vial.

Step 7: Hold the syringe and firmly push the syringe away. The syringe adaptor will remain in place.

Step 8: Place the white vial adaptor cap back on the adaptor by pushing firmly until it clicks into place.

The vial must then be swirled gently until the powder has dissolved completely to form a clear, colorless solution.

Avoid shaking or vigorous mixing. If the solution remains cloudy or contains particles, the vial and its contents should be discarded. In case of cloudiness after reconstitution, the solution should be allowed to warm up to room temperature. If cloudiness still persists, discard the vial and its contents.

4. POSSIBLE SIDE-EFFECTS

Side-effects may occur when you are on treatment with ZOMACTON. Contact your doctor or pharmacist if you are not sure.

- Repeated or severe headache
- Problems with vision
- Haemorrhage and/or swelling
- Nausea and/or vomiting

Please consult your doctor at once if you develop a limp, or hip or knee pain.

5. HOW TO STORE ZOMACTON

ZOMACTON is a medicine that can only be obtained with a prescription. The 10 mg/ml solution for injection is sensitive to light and should be kept in the original container or in its original packaging until you are ready to use it. Keep out of the reach of children.

Store in a cool place, not exceeding 25°C. Do not freeze. Once reconstituted, the solution should be used immediately.

Reference: EP2581149B1

List of medicinal products: 
- ZOMACTON 10 mg/ml, powder and solvent for solution for injection (300 mg)
Its contents should be discarded. In case of cloudiness after refrigeration, the solution should be avoided shaking or vigorous mixing. If the solution remains cloudy or contains particles, the vial and its contents should be discarded. In case of cloudiness after refrigeration, the solution should be avoided shaking or vigorous mixing. If the solution remains cloudy or contains particles, the vial and its contents should be discarded.

**Administration**

If you forget to take ZOMACTON:

- Do not take a double dose to make up for a forgotten dose.
- If you have a hypoglycaemic attack (low blood sugar level) which can cause dizziness, confusion and blurred vision. Although the long-term effectiveness of the treatment will not be affected, you should consult your doctor if this happens.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, ZOMACTON can cause side effects, although not everybody gets them.

- **Injecting growth hormone under the skin may lead to an increase or decrease of fat as well as punctual bloating and bruising (purple discoloration of the skin) at the site of administration. It is therefore recommended to frequently change the site of administration.**
- **On rare occasions, patients may develop pain and an itchy rash at the site of injection.**

**Very commonly reported side effects (more than 1 out of 10 patients experience the side effect):**

- **Blurred vision.** Although the long-term effectiveness of the treatment will not be affected, you should consult your doctor if this happens.
- **Numbness, tingling, burning or creeping on the skin (paresthesia).**

**Uncommonly reported side effects (less than 1 out of 100 but more than 1 out of 1000):**

- **Abnormal blood pressure (hypertension).**
- **An immune reaction to the growth hormone, which may show up in a blood test (antibody building).**
- **Injection site pain.**
- **Injection site swelling.**
- **Injection site bruising.**
- **Injection site warmth.**
- **Injection site mass.**
- **Injection site reaction (including skin reactions, skin atrophy, dermatitis exfoliavit, urticaria, hirsutism, skin hyperpigmentation).**

**Commonly reported side effects (less than 1 out of 10 but more than 1 out of 100):**

- **Muscle pain (myalgia).**
- **Diabetes mellitus type II.**
- **High blood pressure (hypertension).**
- **Muscle pain (myalgia).**
- **Headache.**
- **Numbness, tingling, burning or creeping on the skin (paresthesia).**

**Children and adults:**

- **Rigidity of the spine (hypothyroidism).**
- **Swelling of the feet and ankles.**
- **Muscle pain (myalgia).**
- **Diabetes mellitus type II.**
- **High blood pressure (hypertension).**
- **Injection site reaction (including skin reactions, skin atrophy, dermatitis exfoliavit, urticaria, hirsutism, skin hyperpigmentation).**

**Children only:**

- **Numbness, tingling, burning or creeping on the skin (paresthesia).**
- **Urinary incontinence, haematuria, polyuria, increased thirst, nocturnal polyuria.**
- **Skin eruptions, skin infection, skin irritation.**
- **An immune reaction to the growth hormone, which may show up in a blood test (antibody building).**
- **Injection site reaction (including skin reactions, skin atrophy, dermatitis exfoliavit, urticaria, hirsutism, skin hyperpigmentation).**

**Adults only:**

- **Numbness, tingling, burning or creeping on the skin (paresthesia).**
- **Urinary incontinence, haematuria, polyuria, increased thirst, nocturnal polyuria.**
- **Skin eruptions, skin infection, skin irritation.**
- **An immune reaction to the growth hormone, which may show up in a blood test (antibody building).**
- **Injection site reaction (including skin reactions, skin atrophy, dermatitis exfoliavit, urticaria, hirsutism, skin hyperpigmentation).**

Very rarely reported side effects (less than 1 out of 10,000):

- **Children only:**
  - **Localized pain (the occurrence appears to be more common than in children in the general population).**
  - **Abnormal breasts enlargement (gynaecomastia).**

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**Reporting of side effects:**

If you get any side effects, talk to your doctor or nurse. This includes any side effects not listed in this leaflet. You can also report side effects directly (see below). By reporting side effects you can help provide more information on the safety of this medicine.

**5. HOW TO STORE ZOMACTON**

Keep out of reach of children.

- **Do not use ZOMACTON after the expiry date which is stated on the packaging.** The expiry date refers to the last day of that month.
- **Store in a refrigerator at 2°C - 8°C.** Keep in the outer carton in order to protect it from light.

If the mixture is cloudy when you take it out of the refrigerator, allow the solution to warm up to room temperature. If the mixture is still cloudy or becomes coloured, discard the vial and its contents.

**Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.**

**6. FURTHER INFORMATION**

*What ZOMACTON contains*

- **The active substance is somatropin 10 mg (10 mg/ml after reconstitution).**

- **The other ingredients are:**
  - Powder: Mannitol, disodium phosphate dodecahydrate, sodium dihydrogen phosphate-dihydrate.
  - Solvent: Water for injections and Microcrystals.

*What ZOMACTON looks like and contents of the pack*

- **The product is a powder and solvent for solution for injection.**
- **The powder is white to off white in colour.**
- **When dissolved in the solvent provided, a clear, colourless solution is formed.**

*ZOMACTON is presented in pack sizes of 1, 3 and 5 and consist of:*

- **10 mg somatropin in vial and 1 ml solvent in syringe with solvent transfer connector or vial adaptor.**

- **Not all pack sizes may be marketed.**

**Marketing Authorisation Holder (UK):**

- **Ferring Pharmaceuticals Ltd.**
  - Dryden Hall, Church Road
  - West Dryden UB7 7PS, UK
  - PL 03194/0104

**Marketing Authorisation Holder (Ireland):**

- **Ferring Ireland Ltd.**
  - United Drug House, Magna Drive
  - Magna Business Park, Citywest Road
  - Dublin 24, Ireland
  - PA 1083/83

**Manufacturer:**

- **Ferring GmbH**
  - Wildbad T, D-24109, Kiel
  - Germany

This leaflet was last revised in December 2014.