Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

The dispensing of this medicine requires a doctor's prescription

ZOMACTON® 10 mg

Powder and solvent for reconstituting a solution for subcutaneous injection.

Composition:
Each vial of powder contains somatropin 10 mg.
After adding the solvent, the vial contains a somatropin solution with a concentration of 10 mg/ml.

Inactive ingredients: See section 6 'Additional Information'.

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have further questions, refer to your doctor or pharmacist.
This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

1. What is this medicine intended for?

Children:
- short stature due to non-secretion or inadequate secretion of pituitary growth hormone or Turner's syndrome.
- short stature due to renal insufficiency.

Therapeutic group: Somatropin is a recombinant growth hormone.

2. Before using this medicine

Do not use the medicine:
- If you are sensitive (allergic) to the active ingredient or to any of the other ingredients that this medicine contains (see section 6).
- Do not use Zomacton 10 mg and tell your doctor if you have an active malignant tumor. Malignant tumors must be inactive before beginning treatment. You must complete anti-cancer treatment before beginning treatment with Zomacton 10 mg.
- In children where bone growth is completed (with closed epiphyses).
- If you have a severe illness following complications of an open heart or abdominal surgery, multiple injuries from an accident or respiratory failure.
- In children with chronic kidney disease at the time of kidney transplantation.

Special warnings about using this medicine:
Before treatment with the medicine, consult your doctor
- Treatment with Zomacton 10 mg must be conducted under supervision of a doctor who is specialized in treating patients with growth problems.
- Zomacton 10 mg contains a preservative called metacresol. In extremely rare cases the presence of metacresol can cause inflammation (swelling) in the muscles. If you feel pain at the injection site or in your muscles, see your doctor.
- Do not use Zomacton 10 mg in patients with Prader-Willi syndrome, unless they also have a growth hormone deficiency.
- If you have a family history of diabetes mellitus, your doctor may monitor blood sugar levels.
- If you have diabetes, your sugar levels must be closely monitored and the dose of your sugar balancing medicines may need to be adjusted. You doctor will tell you if this is necessary.
- If you suffer from growth hormone deficiency secondary to a brain injury (intracranial lesion), you must be under constant supervision for possible progression or recurrence of the underlying disease. If this condition is confirmed, your doctor will tell you whether you should stop taking this medicine.
- If you have had a serious disease such as cancer. Treatment with Zomacton 10 mg may cause your illness return or get worse. If you notice any worrying symptoms consult your doctor immediately.
- If you are regularly taking medicines of the glucocorticoids class, consult your doctor since the dose of these medicines may need to be adjusted.
- Treatment with Zomacton 10 mg may cause low levels of thyroid hormone. This condition must be treated. Your doctor will periodically monitor your thyroid function during treatment with Zomacton 10 mg.
- Some children with growth hormone deficiency developed leukemia (a condition in which the number of white blood cells increases), unrelated to their growth hormone treatment. However, there is no evidence that incidence of leukemia in growth hormone patients is higher when there are no predisposing factors. No cause-and-effect relationship with growth hormone treatment has been proven.
- If you have post-surgical complications, trauma or acute respiratory failure, consult your doctor.
- If you must undergo surgery, or have been seriously injured in an accident, or have a serious illness, your doctor may re-evaluate the treatment.
- Children who have stomach ache and are being treated with somatropin, must be examined for inflammation of the pancreas (pancreatitis).

If as a result of treatment with Zomacton 10 mg you develop one of the following reactions, see a doctor or go to an emergency room immediately:
- Severe or repeated headaches
- Problems with vision
- Nausea and/or vomiting

If you develop pain in your hip or knee, or start limping consult your doctor.

Other medicines and Zomacton 10 mg
If you are taking or have recently taken other medicines, including nonprescription medications and nutritional supplements, tell your doctor or pharmacist, particularly tell your doctor or pharmacist if you are taking:
- Steroids as a result of insufficient production of ACTH (adrenocorticotrophic hormone); steroid dose must be adjusted when given together with Zomacton 10 mg.
- High doses of androgens, estrogens, or anabolic steroids might diminish final height.
- Prescription medicines for chronic treatment such as steroids, epilepsy medicines, and medicines for suppressing the immune system.
- Insulin, dose must be checked to ensure continued control of diabetes. Your doctor will instruct you accordingly.

Pregnancy and breastfeeding
Do not use this medicine during pregnancy or breastfeeding. Consult your doctor before taking any medicine when you are pregnant or breastfeeding.

Driving and using machines
This medicine does not affect your ability to drive or use machines.

3. How to use this medicine?

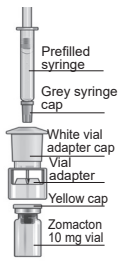
Always use according to the doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how you should use this medicine.
Only your doctor will determine your dose and how you should take the medicine.
Dosage is individual and adjusted for each patient.
Do not exceed the recommended dose.

This medicine is administered by subcutaneous injection (under the skin) using the ZomaJet needle-free injection device.

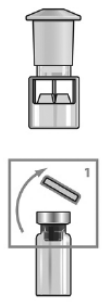
Instructions for use with the needle-free device are provided in the instruction manual supplied with the device, and by personal training from the healthcare professionals.
Instructions for reconstitution
Zomacton 10 mg is a powder and it must be reconstituted using only the solvent supplied in the same package.
Reconstitute the Zomacton 10 mg/ml solution by adding 1 ml of solvent to Zomacton 10 mg powder, as described below.

Instructions for preparing Zomacton 10 mg growth hormone solution:
Note that the figures below illustrate reconstituting a solution intended for injection with a ZomaJet needle-free device, using a vial adapter

1. Wash your hands, open the package, and look through the package contents.



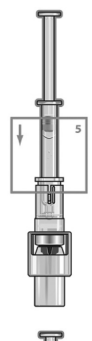
2. Remove the yellow plastic cover from the powder vial (Figure 1).



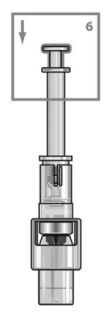
3. Place the plastic adapter in the center of the vial with the tip pointing down. Push the adapter down until it slides into position; be sure to place the adapter tip in the center of the rubber seal of the vial (Figure 2).

4. Remove the white cap from the adapter and the grey cap from the solvent syringe (Figures 3 and 4).

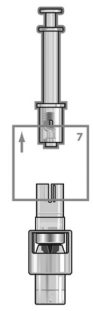
5. Place the powder vial on a level surface and grip the adapter. Insert the syringe into the adapter by pressing down (Figure 5).



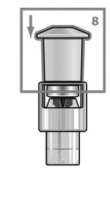
6. Push the plunger in slowly. Make sure to completely empty the syringe into the vial (Figure 6).



7. Grip the vial and pull out the syringe. Keep the adapter in place (Figure 7).



8. Replace the white cap on the adapter by pressing firmly until it slides into place (Figure 8).



9. Swirl the contents of the vial with a gentle rotary motion until completely dissolved and you have a clear, colorless solution.

Store the vial in an upright position in the refrigerator at a temperature of 2°-8°C.
Do not shake or mix vigorously. If the solution is cloudy or there are particles in it, do not use it; it must be discarded.
If the solution becomes cloudy after storing in the refrigerator, leave the vial outside of the refrigerator until it reaches room temperature. If the solution remains cloudy or there are particles in it, do not use it.

If you have accidentally taken an overdose, or if a child has accidentally swallowed some medicine, go immediately to a doctor or to a hospital emergency room and bring the medicine package with you. A Zomacton 10 mg overdose can cause a drop in blood sugar level (hypoglycemia) and then a rise in blood sugar level (hyperglycemia). Repeated Zomacton 10 mg overdose may have an unpredictable effect.

If you forget to take this medicine at the scheduled time, do not take a double dose. Take the next dose at the usual time and consult your doctor. You may experience a drop in blood sugar (hypoglycemia) which causes dizziness, confusion, and blurred vision. Although the long-term effect of this treatment will not be affected, consult your doctor if these symptoms occur.
Persist with the treatment as recommended by your doctor.
Even if your health improves, do not stop taking this medicine without consulting your doctor or pharmacist.

Do not take medicines in the dark! Check the label and dose each time you take a medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or the pharmacist.

4. Side effects

Like all medicines, using Zomacton 10 mg may cause side effects in some people. Do not be alarmed by this list of side effects. You may not experience any of them.

Injecting growth hormone under the skin may reduce or raise the levels of subcutaneous fat at the injection site; there may also be bleeding which will appear as spots and bruises on the skin (purple marks on the skin) at the injection site. It is therefore advisable to frequently change the injection site. In rare cases patients may develop pain or an itchy rash at the injection site.

Very common side effects (appear in more than one user out of ten)
Adults only:
- Edema caused by fluid build-up mainly in the hands and feet.
- Slight rise in blood sugar level (hyperglycemia).
- Joint pain (arthralgia).
- Muscle pain (myalgia).
- Headache.
- Numbness, tingling, burning, or creeping sensation (paresthesia) on the skin.

Common side effects (appear in 1-10 users out of 100)
Children and adults:
- Hypothyroidism.
- Immune reaction to growth hormone, which can be detected in a blood test indicating the appearance of growth hormone antibodies.
- Headache.
- Increased muscle tone (hypertonia).

Children only:
- Edema caused by fluid build-up mainly in the hands and feet.
- Reactions at the injection site.
- Weakness.
- Glucose intolerance.
- Joint pain.
- Muscle pain.

Adults only:
- Stiffness in the arms and/or legs.
- Difficulty falling asleep or sleep disorders (insomnia).

Uncommon side effects (appear in 1-10 users out of 1,000)
Adults and children:
- Anemia.
- Fast heart rate (tachycardia).
- Dizziness (vertigo).
- Double vision (diplopia).
- Edema of the optic nerve head (papilledema).
- Vomiting, flatulence, stomach ache, nausea.
- Weakness.
- Atrophy (thinning) of tissue at the injection site, bleeding in the injection site, lump at the injection site, thickening of tissue at the injection site (hypertrophy).
- Decline in blood sugar level (hypoglycemia).
- Rise in phosphorus level (hyperphosphatemia).
- Muscle atrophy.
- Bone pain.
- Carpal tunnel syndrome.
- Malignant tumors.
- Sleepiness.
- Involuntary eye movement (nystagmus).
- Personality disorders.
- Urinary incontinence, blood in the urine, excessive volume of urine (polyu increased frequency of urination, and abnormal urination.
- Side effects at the injection site (such as: thinning of the fatty layer under the s skin atrophy, skin irritation, allergic skin reaction (urticaria), excessive body h excessive skin proliferation (hypertrophy)).

Children only:
- Stiffness in hands and legs.

Adults only:
- Hypertension.

Rare side effects (appear in 1-10 users out of 10,000)
Adults and children:
- Diarrhea.
- Abnormal results in kidney function test.
- Type II diabetes.
- Prickling or numbness in certain parts of the body (neuropathy).
- Fluid build-up around the brain tissue (presents as severe headache, blurred vis nausea and/or vomiting).

Children only:
- Hypertension.
- Difficulty falling asleep, sleep disorders (insomnia).
- Numbness, tingling, burning or creeping sensation on the skin (paresthesia).

Very rare side effects (appear in less than one user out of 10,000)
Children only:
- Leukemia (disease incidence among children is not greater than its incidence in general population).
- Abnormally enlarged breasts (gynecomastia).

If you experience any side effect, if any side effect gets worse, or if y experience a side effect not mentioned in this leaflet, consult your doc

Reporting side effects
You can report side effects to the Ministry of Health (MoH) by following the 'Reporting Side Effects of Medication' on the MoH home page (www.health.go which links to an online form for reporting side effects. You can also use this l https://sideeffects.health.gov.il

5. How to Store the Medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, closed place out of the reach and sight of children and/or infants. Do not ind vomiting unless explicitly instructed to do so by your doctor.
- Do not use this medicine after the expiry date (exp. date) stated on the package. expiry date refers to the last day of that month.
- Before reconstitution: Store in the refrigerator, at a temperature of 2°-8°C. To pro it from light store in the original box.
- After reconstitution: Be sure to keep the vial in the refrigerator at a temperatur 2°-8°C in an upright position. Use Zomacton 10 mg within 28 days of reconstitut At the end of this period discard the prepared vial.

6. Additional information

In addition to the active ingredient this medicine also contains:
mannitol, disodium phosphate dodecahydrate, sodium dihydrogen phosphate dehydr

Each syringe with solvent contains: m-cresol, water for injection.

What the medicine looks like and what are the contents of the package:
This medicine is a powder and a solvent for reconstituting an injection solution; powder is white and is packaged in a vial. The solvent is packaged in a prefi syringe. The medicine package also contains an adapter for the powder vial.

License holder name and address: Ferring Pharmaceuticals Ltd., 8 Hashita Industrial Park Caesarea 3088900.

Manufacturer name and address: Ferring GmbH, Kiel, Germany.

Revised in August 2020.

Registration number of the medicine in the National Drug Registry of the Minis of Health: 144 21 31997.