

Leaflet	Zolvar® (EXP) Zoledronic acid
Size	160 x 160 mm
Date	14.01.09.12

Colors:
● PANTONE 293 U

160 mm

160 mm

Zoledronic Acid
Zolvar® 4mg/5ml
Concentrate for solution for infusion



Read all of this leaflet carefully before you are given this medicine because it contains important information for you. Keep this leaflet. You may need to read it again. If you have any further questions, ask your doctor, pharmacist or nurse.

What Zol-var® is and what it is used for:

The active substance in Zol-var® is zoledronic acid, which belongs to a group of substances called bisphosphonates. Zoledronic acid works by inhibition of bone resorption. zoledronic acid inhibits osteoclastic activity and induces osteoclast apoptosis. It is used in:

hypercalcemia of malignancy, multiple myeloma, bone metastases from solid tumors, Paget's disease, prevention and treatment of osteoporosis.

What you need to know before you are given Zol-var®

Follow carefully all instructions given to you by your doctor. Your doctor will carry out blood tests before you start treatment with Zoledronic acid and will check your response to treatment at regular intervals.

You should not be given Zol-var®

- ▶ if you are allergic to zoledronic acid, another bisphosphonate (the group of substances to which Zoledronic acid belongs), or any of the other ingredients of this medicine.

Warnings and precautions

Talk to your doctor before you take Zol-var®

- ▶ if you have or had a kidney problem.
- ▶ Atypical femur fractures (AFF) have been reported with this medication. Contact your doctor if you experience pain, weakness or discomfort in your thigh, hip or groin as this may be an early indication of a possible fracture of the thigh bone.
- ▶ if you have or had pain, swelling or numbness of the jaw, a feeling of heaviness in the jaw or loosening of a tooth. Your doctor may recommend a dental examination before you start treatment with Zoledronic acid. if you are having dental treatment or are due to undergo dental surgery, tell

your dentist that you are being treated with Zoledronic acid and inform your doctor about your dental treatment.

Other medicines and Zol-var®

Tell your doctor if you are taking, have recently taken or might take any other medicines. It is especially important that you tell your doctor if you are using:

- ▶ Aminoglycosides, Angiogenesis Inhibitors, Calcitonin, Deferasirox, Inhibitors of the Proton Pump, Loop Diuretics, Nonsteroidal Anti-Inflammatory Agents, Thalidomide.

How to prepare and administer Zol-var®

Zol-var® should be diluted in 100 mL of sterile 0.9% Sodium Chloride, or 5% Dextrose, following proper aseptic technique, and administered to the patient by intravenous infusion. It is recommended to infusion the medication intravenously over at least 15 minutes. Zol-var® must not be mixed with calcium or other divalent cation-containing infusion solutions, such as Lactated Ringer's solution, and should be administered in a line separate from all other drugs.

If not used immediately after dilution with infusion media, for microbiological integrity, the solution should be refrigerated at 2°C to 8°C. The refrigerated solution should then be equilibrated to room temperature prior to administration. The total time between dilution, storage in the refrigerator, and end of administration must not exceed 24 hours.

Zoledronic acid must only be given by healthcare professionals. Your doctor will recommend that you drink enough water before each treatment to help prevent dehydration. Carefully follow all the other instructions given to you by your doctor, nurse or pharmacist.

Pregnancy and breast-feeding

You must not be given Zol-var® if you are pregnant. Tell your doctor if you are or think that you may be pregnant.

You must not be given Zol-var® if you are breast-feeding.

Ask your doctor for advice before taking any medicine while you are pregnant or breast-feeding.

Driving and using machines

There have been very rare cases of drowsiness and sleepiness with the use of Zol-var®. You should therefore be careful when driving, using machinery or performing other tasks that need full attention.

160 mm

160 mm

Zolvar® 4mg/5ml

Zol-var® contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose. It is essentially "sodium-free".

How much Zol-var® is given

The usual single dose given is 4 mg. If you have a kidney problem, your doctor will give you a lower dose depending on the severity of your kidney problem.

How often Zol-var® is given

- ▶ If you are being treated for the prevention of bone complications due to bone metastases, you will be given one infusion of Zoledronic acid every three to four weeks.
- ▶ If you are being treated to reduce the amount of calcium in your blood, you will normally only be given one infusion of Zoledronic acid.

Patients whose blood calcium levels are not too high will also be prescribed calcium and vitamin D supplements to be taken each day.

If you are given more Zol-var® than you should be

If you have received doses higher than those recommended, you must be carefully monitored by your doctor. This is because you may develop serum electrolyte abnormalities (e.g. abnormal levels of calcium, phosphorus and magnesium) and/or changes in kidney function, including severe kidney impairment. If your level of calcium falls too low, you may have to be given supplemental calcium by infusion.

Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Some side effects are listed below. **If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.**

Diarrhea, Nausea, Vomiting, Anorexia, Constipation, Anemia,

Dizziness, Fatigue, Skeletal pain, Myalgia, Headache, Insomnia, Back pain, Abdominal pain, Cough, Dyspnea, Atrial fibrillation, Renal damage (kidney impairment), Low level of calcium in the blood, Pain in the mouth, teeth and/or jaw, swelling or nonhealing sores inside the mouth or jaw, discharge, numbness or a feeling of heaviness in the jaw, or loosening of a tooth (These could be signs of osteonecrosis). Severe allergic reaction (shortness of breath, swelling mainly of the face and throat), Cardiac arrhythmia (secondary to hypocalcemia), Low level of phosphate in the blood, Flu-like syndrome (fever, weakness, drowsiness, chills), Conjunctivitis, Low blood pressure, Chest pain, Skin reactions (redness and swelling) at the infusion site, Rash, Itching, High blood pressure, Anxiety, Sleep disturbances, Numbness of the hands or feet, Low counts of white blood cells and blood platelets, Low level of magnesium and potassium in the blood, Increased sweating, Sleepiness, Blurred vision, Fainting, Urticaria, Confusion, Interstitial lung disease.

How to store Zol-var®

Store below 30 °C. Do not freeze. Keep out of the sight and reach of children.

Contents of the pack and other information

The active substance of Zol-var® is zoledronic acid. One ampule contains 4 mg of zoledronic acid (as monohydrate). Zol-var® is for single use only. Only clear and colorless solution free from particles should be used. Zol-var® is supplied as packs containing 1 ampule.



Manufactured by: Varian Pharmed, Tehran - Iran
Exclusive distributor: Aljood pharma scientific bureau