PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

ZOBONE 4 mg/vial powder for solution for infusion
Zoledronic acid (anhydrous)

Contains sugar alcohol (220 mg mannitol per vial)

Read all of this leaflet carefully before you are given ZOBONE.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What ZOBONE is and what it is used for

The active substance of ZOBONE is zoledronic acid, which belongs to a group of substances called bisphosphonates.

Zoledronic acid works by attaching itself to the bone and slowing down the rate of bone change. It is used:

- To prevent bone complications, e.g. fractures, in adult patients with bone metastases (spread of cancer from primary site to the bone).

- To reduce the amount of calcium in the blood in adult patients where it is too high due to the presence of a tumour. Tumours can accelerate normal bone change in such a way that the release of calcium from bone is increased. This condition is known as tumour-induced hypercalcaemia (TIH).

2. What you need to know before ZOBONE is administered

ZOBONE should not be administered to you:

- If you are hypersensitive (allergic) to zoledronic acid, other bisphosphonate medicines used to treat cancer, or any of the other ingredients of ZOBONE listed in section 6.
- If you have severe kidney disease.
- If you are pregnant or breastfeeding (see section 2,“Pregnancy and breastfeeding”).

Warnings and precautions:

Tell your doctor or health care provider before being administered the injection:

- ZOBONE may interfere with your kidney function. Consult your doctor if you experience any changes in your kidney function such as the amount of urine you pass or generalised swelling.
- ZOBONE may alter the levels of calcium, phosphate, magnesium and serum creatinine in your body and you may need treatment for those changes.

Take special care:

- If you have a liver problem.
- If you have a history of or currently suffer from heart problems.
- If you have a history of or currently suffer from pain, swelling or numbness of the jaw, or a “heavy jaw feeling” or loosening of a tooth. Your doctor may recommend a dental examination before you start treatment with ZOBONE.

If you are under dental treatment or will undergo dental surgery, tell your dentist that you are being treated with ZOBONE, and inform your doctor about your dental treatment.

While being treated with zoledronic acid, you should maintain good oral hygiene (including regular teeth brushing) and receive routine dental check-ups.

Contact your doctor and dentist immediately if you experience any problems with your mouth or teeth, such as loose teeth, pain or swelling, or non-healing of sores or discharge, as these could be signs of a condition called osteonecrosis of the jaw.

Patients who are undergoing chemotherapy and/or radiotherapy, who are taking steroids, who are undergoing dental surgery, who do not receive routine dental care, who have gum disease, who are smokers, or who were previously treated with a bisphosphonate (used to treat or prevent bone disorders) may have a higher risk of developing osteonecrosis of the jaw.

ZOBONE treatment should be discontinued if you present with atypical femoral fractures (e.g. where your thigh bone breaks with little or no force).

Your doctor will perform blood tests prior to your treatment with ZOBONE and will check your response to treatment at regular intervals.

Ensure sufficient intake of liquids prior to infusions as directed by your doctor, as this will help prevent dehydration.

If you are being treated with ZOBONE (zoledronic acid), you should not be treated with other medicines that also contain zoledronic acid and are used to treat osteoporosis and other non-cancer diseases of the bone, or any other bisphosphonate, concomitantly.

You may develop severe bone, joint and or muscle pain.

Reduced levels of calcium in the blood (hypocalcaemia), sometimes leading to muscle cramps, dry skin and a burning sensation, have been reported in patients treated with ZOBONE. Irregular heartbeat (cardiac dysrhythmia), seizures, muscle spasm and twitching (tetany) have been reported as secondary to severe hypocalcaemia. In some instances, the hypocalcaemia may be life-threatening. If any of these apply to you, tell your doctor straight away. If you have pre-existing hypocalcaemia, it must be corrected before initiating the first dose of ZOBONE. You will be given adequate calcium and vitamin D supplements.

Take special care if you are an asthmatic patient with known sensitivity to acetylsalicylic acid.

If you are using steroids, if you are on cancer treatment or have an ear infection and you are administered ZOBONE, it may lead to a condition that exposes the bone tissue in your ear.

You may develop flu-like symptoms that include fever, body pain, headache, nausea, vomiting and diarrhoea when you begin treatment with ZOBONE.

Use in elderly patients:

Avoid over-hydration in elderly patients with heart disease.

Children and adolescents:

The safety and efficacy of ZOBONE in paediatric patients have not been established.

Other medicines and ZOBONE:

ZOBONE may interact with other medicines.

Always tell your health care provider if you are taking any other medicines (this includes complementary or traditional medicines).

The following medicines may interact with ZOBONE:

- Loop diuretics (medicine that treats high blood pressure or reduces water retention).
- Calcitonin (a type of medicine used to treat post-menopausal osteoporosis and hypercalcaemia) or aminoglycosides (antibiotics, medicines used to treat severe infections) since the combination of these with bisphosphonates may cause the calcium level in the blood to become too low.
- Medicines that affect the kidneys.
- Certain anticancer medicines (e.g chemotherapy), corticosteroids or anti-angiogenic medicines (treatment used in cancers to stop tumours from growing their own blood vessels) since the combination of these with ZOBONE has been associated with an increased risk of osteonecrosis of the jaw (ONJ).
- Thalidomide (a medicine used to treat a certain type of blood cancer involving the bone).

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving medicine.

DO NOT use ZOBONE if you are pregnant or suspect that you are pregnant. Contact you doctor immediately.

DO NOT use ZOBONE if you are breastfeeding.

Women of child-bearing potential should be advised to avoid becoming pregnant and advised of the potential hazard to the foetus while receiving ZOBONE. There may be a risk of foetal harm e.g. skeletal and other abnormalities if a woman becomes pregnant while receiving ZOBONE therapy.

Driving and using machines:

ZOBONE may impair your ability to drive and use machinery. Take care if you feel dizzy, tired or drowsy while receiving ZOBONE. Do not drive or operate any machinery until you know how ZOBONE affects you.

ZOBONE contains sodium:

This medicine contains less than 1 mmol sodium (23 mg) per unit volume, that is to say essentially ‘sodium-free’.

3. How ZOBONE will be administered

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself ZOBONE. It will be given to you by a person who is qualified to do so, as an intravenous infusion mixed with other intravenous solutions.

The dose of ZOBONE will be different for different patients and may depend on a number of things, including what the medicine is being used for, the patient's size, and whether or not other medicines are also being taken.

Your doctor will recommend that you drink enough water before each treatment to help prevent dehydration.

The usual dose is 4 mg of zoledronic acid.If you are being treated for tumour-induced hypercalcaemia (abnormally high levels of calcium in the body) a dose of 8 mg of zoledronic acid is recommended.

If you have a kidney problem, your doctor will give you a lower dose depending on the severity of your kidney problem.

How ZOBONE is given

ZOBONE is usually given as an infusion into a vein which should last no less than 15 minutes and should be administered as a single intravenous solution in a separate infusion line. In addition, if you do not suffer from hypercalcaemia you will also receive oral supplementary doses of calcium and vitamin D daily.

Your doctor will tell you how long your treatment with ZOBONE will last. If you have the impression that the effect of ZOBONE is too strong or too weak, tell your doctor or pharmacist.

How often is ZOBONE given

If you are being treated to prevent skeletal related events, you will be given one infusion of ZOBONE every 3 to 4 weeks. If you are being treated to reduce the amount of calcium in your blood (for TIH), you will normally only be given one infusion of ZOBONE. Your doctor will decide how often you should receive the infusions.

If you receive more ZOBONE than you should:

Since a health care provider will administer ZOBONE, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to receive ZOBONE:

Since a health care provider will administer ZOBONE, it is unlikely that the dose will be missed.

4. Possible side effects

ZOBONE can have side effects.

Not all side effects reported for ZOBONE are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while receiving ZOBONE, please consult your doctor, pharmacist or other health care provider for advice.

Since the growth of normal body cells may also be affected by ZOBONE, other effects will also occur. Some of these may be serious and must be reported to your doctor. Other effects may not be serious but may cause concern. Some effects may not occur until months or years after the medicine was used.

If any of the following happens, stop receiving ZOBONE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to ZOBONE. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Severe kidney impairment (will normally be determined by your doctor with specific blood tests).
- Pain in the mouth, teeth and/or jaw, swelling or non-healing 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 bone damage in the jaw (osteonecrosis of the jaw [ONJ]).
- Low level of calcium in the blood.
- Irregular heart rhythm (atrial fibrillation) has been seen in patients receiving zoledronic acid.
- Weak or shallow breathing and shortness of breath (bronchoconstriction).

- Hypotension leading to fainting or a sudden temporary loss of consciousness (syncope) or circulatory collapse.
- Severe skin reaction, skin pain, followed by a red or purple skin rash that spreads (especially in the face or upper body) and causes blistering and peeling.
- Excessive thirst and excessive urination along with vomiting and frailty (acquired Fanconi syndrome).
- Tremors.
- Seizures (fits or convulsions).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent:

- Reduced red blood count (anaemia). You may feel tired and pale.
- Headache.
- Irritation or inflammation of the eyes (conjunctivitis).
- Nausea and vomiting.
- Anorexia.
- Decreased appetite.
- Joint aches or stiffness.
- Muscle aches or spasms.
- Generalised pain in bones.
- Fever.
- Tiredness (fatigue).
- Shivering (chills).
- Feeling generally unwell.
- Flushing (warmth, redness or tingly feeling).

- Low levels of phosphate in the blood.

Less frequent:

- A low blood platelet count (thrombocytopenia). You are more prone to bleeding and bruising.
- A type of anaemia where your red and white blood cells and platelets are reduced (leucopenia).
- Low levels of red and white blood cells and platelets (pancytopenia).
- Anxiety.
- Sleep disturbance.
- Confusion.
- Dizziness.
- Loss of taste.
- A decreased or increased sense of touch or sensation.
- Involuntary contraction of muscles that usually results from low calcium levels in the blood (i.e. hypocalcaemia).
- Blurred vision.
- Redness, inflammation or tearing of the eye.
- Slowing of the heartbeat.
- Cough.
- Stomach pain.
- Bloating.
- Diarrhoea.
- Constipation.
- Dry mouth.
- Increased sweating.
- Muscle cramps.

- Presence of blood in the urine.
- Abnormal physical weakness or lack of energy (asthenia).
- Pain and swelling at the site of injection.
- Chest pain.
- Weight increase.
- Low magnesium and potassium levels.
- High blood pressure or low blood pressure

Frequency unknown

- inflammation that affects the tubules of the kidneys and the tissues that surround them (Tubulointerstitial nephritis)

If you notice any side effects not mentioned in the leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ZOBONE.

Suspected adverse reactions can also be reported directly to the Holder of certificate of registration

via email or telephonically: pharmacovigilance.africasme@sunpharma.com or

tel:+27(0) 12 643 2000

5. How to store ZOBONE

- Store at or below 25 °C.
- Keep the vial in the outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use the concentrate for infusion after the expiry date printed on the container or label.
- Return all unused medicine to your pharmacist.

- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

For unopened vials of this medicine:

Shelf life is 24 months.

After first opening:

The reconstituted product may be stored for 24 hours at 25 °C or refrigerated between 2 °C and 8 °C

and must be visually inspected for particulate matter and discolouration.

6. Contents of the pack and other information

What ZOBONE contains:

The active substance is zoledronic acid.

Each vial contains 4 mg zoledronic acid (as zoledronic acid monohydrate).

The other ingredients are:

Mannitol (parenteral grade), sodium citrate dihydrate (buffering agent) and water for injection.

What ZOBONE looks like and contents of the pack:

A white to off-white lyophilised cake in a 5 mL vial.

ZOBONE is packed in a 5 mL clear colourless USP type I tubular glass vial, with a 20 mm grey bromobutyl Igloo RFS (ready for sterilisation) rubber stopper and 20 mm flip off seal with golden brown colour.

Pack size:

1 vial.

Holder of certificate of registration:

Ranbaxy Pharmaceuticals (Pty) Ltd

14 Lautre Road

Stormill, Ext. 1, Roodepoort

Johannesburg 1724

Tel. 012 643 2000

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Access to the corresponding PIL translation: The PIL is available in one other language (Afrikaans), a copy is accessible on the company website: https://sunpharma.com/south-africa-products/

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