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
2. What you need to know before ZOBONE is adminstered
3. How ZOBONE is administered

4. Possible side effects

5. How to store ZOBONE

6. Contents of the pack and other information.

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.

ZOBONE is a treatment used to reduce and delay bone complications due to multiple myeloma (cancer of the white blood cells) and bone metastases (bone growths) from solid tumours; used together with anticancer medicines. ZOBONE is also used if you have prostate cancer and experience bone growths despite receiving hormonal therapy. ZOBONE is not an anticancer therapy.

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 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.

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.

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.

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 your baby, please consult your doctor, pharmacist or other health care provider for advice before receiving ZOBONE.

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.

ZOBONE contains sodium:

This medicine contains less than 1 mmol sodium (23 mg) per unit

volume, that is to say essentially ‘sodium-free’.

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.

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.

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.

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.

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.

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 "**Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of ZOBONE.

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

This leaflet was last revised:

22 April 2022

Registration number:

42/34/0664

Date of registration:

4 March 2011

Namibia: NS2 13/34/0190

Pasientinligtingstuk for ZOBONE

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS

S4

ZOBONE 4 mg/flessie poeier vir oplossing vir infusie

Soledronoësuur (anhidriese)

Bevat suikeralkohol (220 mg mannitol per flessie)

Lees hierdie hele inligtingstuk noukeurig deur voordat ZOBONE aan jou toegedien word.

- Hou hierdie inligtingstuk. Dit mag vir jou nodig wees om dit weer te lees.
- Vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer as jy verdere vrae het.
- This medisyne is vir jou persoonlik voorgeskryf en jy moet nie jou medisyne met enige ander persoon deel nie. Dit kan skadelik vir hulle wees, selfs as hulle simptome dieselfde as joune is.

Wat is in hierdie inligtingstuk:

1. Wat ZOBONE is en waarvoor dit gebruik word
2. Wat jy moet weet voordat ZOBONE aan jou toegedien word
3. Hoe word ZOBONE toegedien

4. Moontlike newe-effekte

5. Hoe om ZOBONE te bewaar

6. Inhoud van die verpakking en ander inligting.

1. Wat ZOBONE is en waarvoor dit gebruik word

Die aktiewe bestanddeel van ZOBONE is soledronoësuur, wat aan ‘n groep stowwe behoort, wat bekend staan as bisfosfonate.

ZOBONE is ‘n behandeling wat gebruik word om beenkomplikasies as gevolg van veelvoudige miëloom (kanker van die witbloedselle) en beenmetastase (beengroeisel) van soliede tumore te verminder of te vertraag; gebruik saam met antikanker medisyne. ZOBONE word ook gebruik as jy prostaatkanker het en beengroeisels kry, ten spyte daarvan dat jy hormoonterapie ontvang. ZOBONE is nie ‘n antikanker-terapie nie.

2. Wat jy moet weet voordat ZOBONE aan jou toegedien word

ZOBONE moet nie aan jou toegedien word nie:

- As jy hipersensitief (allergies) is vir soledronoësuur, ander bisfosfonaat-medisyne wat gebruik word om kanker te behandel, of enige van die ander bestanddele van ZOBONE gelys in afdeling 6.
- As jy ernstige niersiekte het.
- As jy swanger is of borsvoed (sien afdeling 2, “Swangerskap en borsvoeding”) .

Waarskuwings en voorsorgmaatreëls:

Lig jou dokter of gesondheidsorgverskaffer in voordat die inspuiting aan jou toegedien word:

- ZOBONE kan inmeng met jou nierfunksie. Raadpleeg jou dokter as jy enige veranderinge in jou nierfunksie ervaar, soos die hoeveelheid urine wat jy passeer of algemene swelling.
- ZOBONE kan die vlakke van kalsium in jou liggaam verander en jy mag behandeling vir daardie veranderinge benodig.

Tref spesiale voorsorg:

- As jy ‘n lewerprobleem het.
- As jy ‘n geskiedenis het, of huidiglik, aan hartprobleme ly.
- As jy ‘n geskiedenis het, of huidiglik, aan pyn, swelling of gevoelloosheid van die kakebeen, of ‘n “swaar gevoel in die kakebeen” ly of ‘n tand het wat losgeraak het. Jou dokter kan aanbeveel dat ‘n tandartsondersoek gedoen word voordat jou behandeling met ZOBONE begin.

As jy onder tandheelkundige behandeling is of tandheelkundige chirurgie moet ondergaan, moet jy jou tandarts inlig dat jy met ZOBONE behandel word en lig jou dokter in oor as jy tandheelkundige behandeling ontvang.

Lig jou dokter en tandarts onmiddellik in as jy enige probleme met jou mond of tande, soos los tande, pyn of swelling, of sere wat nie gesond word nie of afskeiding ervaar, aangesien hierdie tekens kan wees van ‘n toestand wat bekend staan as osteonekrose van die kakebeen.

Pasiënte wat chemoterapie en/of radioterapie ontvang, wat steroïede gebruik, wat tandheelkundige chirurgie ondergaan, wat nie roetine tandsorg ontvang nie, wat tandvleissiekte het, wat rokers is, of wat voorheen met ‘n bisfosfonaat behandel is (gebruik om beenversteurings te behandel of te voorkom) kan ‘n groter risiko hê om osteonekrose van die kakebeen te ontwikkel.

Behandeling met ZOBONE moet gestaak word as jy met atipiese femorale frakture (bv. waar jou dybeen met min of geen krag breek) presenteer.

Jou dokter sal bloedtoetse uitvoer voor jou behandeling met ZOBONE en sal jou reaksie op behandeling met gereelde intervalle monitor.

Verseker voldoende inname van vloeistowwe voor infusies, soos aanbeveel deur jou dokter, aangesien dit dehidrasie sal voorkom.

As jy met ZOBONE (soledronoësuur) behandel word, moet jy nie met ander medisyne wat ook soledronoësuur bevat en gebruik word om osteoporose te behandel en ander nie-kanker siektes van die been, of enige ander bisfosfonaat, gelyktydig behandel word nie.

Verlaagde vlakke van kalsium in die bloed (hipokalsemie), wat somtyds lei tot spierkrampe, droë vel en ‘n branderige sensasie, is aangemeld by pasiënte wat met ZOBONE behandel is. Onreëlmatige hartklop (kardiale disritmie), toevalle, spierspasma en senutrekkings (tetanie) is aangemeld as sekondêr tot ernstige hipokalsemie. In sommige gevalle kan die hipokalsemie lewensbedreigend wees. As enige van hierdie op jou van toepassing is, moet jy jou dokter dadelik vertel. As jy voorafbestaande hipokalsemie het, moet dit reggestel word voordat die eerste dosis van ZOBONE toegedien word. Daar sal voldoende kalsium en vitamien-D aanvullers aan jou voorgeskryf word.

Tref spesiale voorsorg as jy ‘n asmatiese pasiënt is met bekende sensitiwiteit teen asetielsalisielsuur.

Gebruik by bejaarde pasiënte:

Vermy oor-hidrasie by bejaarde pasiënte met hartsiekte.

Kinders en adolessente:

Die veiligheid en doeltreffendheid van ZOBONE in pediatriese pasiënte is nie vasgestel nie.

Ander medisyne en ZOBONE:

ZOBONE kan met ander medisyne inwerk.

Lig jou gesondheidsorgverskaffer altyd in as jy ander medisyne gebruik. (Dit sluit alle aanvullende of tradisionele medisyne in).

Die volgende medisyne kan ZOBONE inwerk:

- Lusdiuretika (medisyne wat hoë bloeddruk behandel of waterretensie verminder).
- Kalsitonien (‘n soort medisyne wat gebruik word om post-menopousale osteoporose en hiperkalsemie te behandel) of aminoglikosiede (antibiotika, medisyne wat gebruik word om ernstige infeksies te behandel), aangesien die kombinasie van hierdie met bisfosfonate kan veroorsaak dat die kalsiumvlak in die bloed te laag kan daal
- Medisyne wat die niere affekteer.

- Sekere antikanker medisyne (bv. chemoterapie), kortikosteroïede of anti-angiogeniese medisyne (gebruik in behandeling van kanker om te keer dat tumore hulle eie bloedvate vorm) aangesien die kombinasie van hierdie met ZOBONE geassossieer word met ‘n verhoogde risiko van osteonekrose van die kakebeen (ONJ).
- Talidomied (‘n medisyne wat gebruik word om ‘n sekere soort bloedkanker te behandel waar been betrokke is).

Swangerskap en borsvoeding:

As jy swanger is of jou baba borsvoed, moet jy asseblief jou dokter, apteker of ander gesondheidsorgverskaffer raadpleeg vir advies voordat jy ZOBONE ontvang.

MOENIE ZOBONE gebruik as jy swanger is of vermoed dat jy swanger is nie. Kontak jou dokter onmiddellik.

MOENIE ZOBONE gebruik as jy borsvoed nie.

ZOBONE bevat natrium:

Hierdie medisyne bevat minder as 1 mmol natrium (23 mg) per eenheidsvolume, dit wil sê feitlik ‘natriumvry’.

Bestuur en gebruik van masjinerie:

ZOBONE kan inmeng met jou vermoë om te bestuur of masjinerie te hanteer. Tref voorsorg as jy duiselig voel, moeg of lomerig is terwyl jy ZOBONE ontvang. Moenie bestuur of enige masjinerie

hanteer nie totdat jy weet hoe ZOBONE jou affekteer.

3. Hoe ZOBONE toegedien sal word

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.

Daar sal nie van jou verwag word om ZOBONE aan jouself toe te dien nie. Dit sal deur ‘n gekwalifiseerde persoon aan jou toegedien word as ‘n intraveneuse infusie wat gemeng is met ander intraveneuse oplossings.

Die dosis van ZOBONE sal verskillend wees vir verskillende pasiënte en kan afhang van ‘n aantal faktore, insluitend waarvoor die medisyne gebruik word, die pasiënt se bou en of ander medisyne geneem word, of nie.

Die normale dosis is 4 mg soledronoësuur.

As jy behandel word vir tumor-geïnduseerde hiperkalsemie (abnormale hoë vlakke van kalsium in die liggaam) word ‘n dosis van 8 mg soledronoësuur aanbeveel.

As jy ‘n nierprobleem het, sal jou dokter ‘n laer dosis aan jou toedien afhangende van hoe ernstig jou nierprobleem is.

Jou dokter sal jou inlig oor hoe lank jou behandeling met ZOBONE sal duur. Praat met jou dokter of apteker as jy onder die indruk is dat die effek van ZOBONE te sterk of te swak is.

As jy meer ZOBONE ontvang het as wat jy behoort te ontvang:

Aangesien ‘n gesondheidsorgverskaffer ZOBONE sal toedien, sal hy/sy die dosis kontroleer. In die geval van oordosering, sal jou dokter egter die oordosering bestuur.

As jy vergeet het om ZOBONE te ontvang:

Dit is onwaarskynlik dat ‘n dosis oorgeslaan sal word, aangesien ‘n gesondheidsorgverskaffer ZOBONE toedien.

4. Moontlike newe-effekte

ZOBONE kan newe-effekte hê.

Nie alle newe-effekte wat vir ZOBONE aangemeld word, is in hierdie inligtingstuk opgeneem nie. Indien jou algemene gesondheid versleg of as jy enige ongunstige effekte ervaar terwyl jy ZOBONE ontvang, moet jy asseblief jou dokter, apteker of ander gesondheidsorgverskaffer raadpleeg vir advies.

Aangesien die groei van normale liggaamselle ook deur ZOBONE geaffekteer kan word, sal ander effekte ook voorkom. Sommige van hierdie mag ernstig wees en moet aan jou dokter vertel word. Ander effekte mag nie ernstig wees nie, maar kan die oorsaak van bekommernis wees. Sommige effekte mag eers maande of jare nadat die medisyne gebruik was, voorkom.

As enige van die volgende gebeur, moet die toediening van ZOBONE gestaak word en jou dokter moet onmiddellik in kennis gestel word of jy moet na die noodgevalle afdeling by jou naaste

hospitaal gaan:

- Swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat probleme om te sluk of asem te haal kan veroorsaak.
- Uitslag of gejeuk.
- Floute.

Hierdie is almal baie ernstige newe-effekte. As jy dit het, kon jy ‘n ernstige reaksie teen ZOBONE gehad het. Jy mag dringende mediese aandag of hospitalisasie benodig.

Lig jou dokter onmiddellik in of gaan na die noodgevalle afdeling by jou naaste hospitaal as jy enige van die volgende opmerk:

- Ernstige nierversaking (sal gewoonlik deur jou dokter bepaal word deur spesifieke bloedtoetse uit te voer).
- Pyn in die mond, tande en/of kakebeen, swelling of seertjies in die mond of kakebeen wat nie gesond word nie, afskeiding, gevoelloosheid of ‘n swaar gevoel in die kakebeen of as ‘n tand losraak. Hierdie kan tekens wees van beenskade in die kakebeen (osteonekrose van die kakebeen [ONJ]).
- Lae vlak van kalsium in die bloed.
- OnreëImatige hartritme (atriale fibrillasie) is waargeneem in pasiënte wat soledronoësuur ontvang.
- Swak of vlak asemhaling en kortasemigheid (brongokonstriksie).
- Hipotensie wat tot floute lei of ‘n skielike verlies aan bewussyn (sinkopee) of sikulatoriese ineenstorting.

- Ernstige velreaksie, pyn in die vel, gevolg deur ‘n rooi of pers veluitslag wat versprei (veral in die gesig of boonste deel van die liggaam) en blasievorming en afskilfering veroorsaak.
- Uitermatige dorsheid en uitermatige urinering saam met braking en broosheid (verworwe Fanconi-sindroom).
- Bewing.
- Toevalle (aanvalle of konvulsies).

Hierdie is almal ernstige newe-effekte. Jy mag dringende mediese aandag benodig.

Lig jou dokter in as jy enige van die volgende opmerk:

Dikwels:

- Verlaagde rooibloedseltelling (anemie). Jy kan moeg voel en bleek lyk.
- Hoofpyn.
- Irritasie of inflammasie van die oë (konjunktivitis).
- Naarheid en braking.
- Anoreksie.
- Verlaagde aptyt.
- Gewrigspyne of styfheid.
- Spierpyn or spasma.
- Algemene pyn in die bene.
- Koors.
- Moegheid (uitputting).
- Bewerigheid (koue rillings).
- Voel oor die algemeen nie goed nie.

- Blosing (warmte, rooiheid of tintelende gevoel).
- Lae vlakke van fosfaat in die bloed.

Minder algemeen:

- ‘n Lae bloedplaatjietelling (trombositopenie). Jy is meer geneig tot bloeding en kneusing.
- ‘n Soort anemie waar jou rooi- en witbloedselle en plaatjies verminder is (leukopenie).
- Lae vlakke van rooi- en witbloedselle en plaatjies (pansitopenie).
- Angstigheid.
- Slaapversteuring.
- Verwarring.
- Duiseligheid.
- Verlies van smaak.
- ‘n Verlaagde of verhoogde gewaarwording van aanraking of sensasie.
- Onwillekeurige sametrekking van spiere wat gewoonlik ‘n resultaat is van lae kalsiumvlakke in die bloed (bv. hipokalsemie).
- Belemmerde sig.
- Rooiheid, inflammasie of tranerigheid van die oog.
- Hartklop word stadig.
- Hoes.
- Maagpyn.
- Opgebalsenheid.
- Diarree.
- Hardlywigheid.

- Droë mond.
- Sweet meer.
- Spierkrampe.
- Teenwoordigheid van bloed in die urine.
- Abnormale fisiese swakheid of verlies aan energie (astenie).
- Pyn en swelling by die inspuitplek.
- Borskaspyn.
- Gewigstoename.
- Lae magnesium- en kaliumvlakke.

As jy enige newe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie, moet jy jou dokter of apteker daarvan in kennis stel.

Aanmelding van newe-effekte:

As jy newe-effekte ervaar, moet jy jou dokter of apteker inlig. Jy kan ook newe-effekte by SAHPRA SAHPRA *via* die "**Adverse Drug Reaction Reporting Form**" aanmeld, wat aanlyn beskikbaar is onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van ZOBONE te verskaf.

5. Hoe om ZOBONE te bewaar

- Bewaar by of onder 25 °C.
- Hou die flessie in die buitenste karton tot benodig vir gebruik.

- BEWAAR ALLE MEDISYNE BUITE DIE BEREIK VAN KINDERS.
- Moenie die konsentraat vir infusie ná die vervaldatum, soos gedruk op die houer of etiket, gebruik nie.
- Bring alle ongebruikte medisyne na jou apteker toe terug.
- Moenie van ongebruikte medisyne in dreinering- of rioleringstelsels (bv. toilette) ontslae raak nie.

Vir flessies van hierdie medisyne wat nie oopgemaak is nie:

Rakleeftyd is 24 maande.

Nadat dit die eerste keer oopgemaak is:

Die hersaamgestelde produk kan vir 24 uur teen 25 °C of in ‘n yskas tussen 2 °C en 8 °C bewaar word en moet visueel geïnspekteer word vir deeltjies en verkleuring.

6. Inhoud van die verpakking en ander inligting

Wat ZOBONE bevat:

Die aktiewe bestanddeel is soledronoësuur.

Elke flessie bevat 4 mg soledronoësuur (as soledronoësuur-monohidraat).

Die ander bestanddele is:

Mannitol (inspuitbare graad), natriumsitraat-dihidraat (buffermiddel) en water vir inspuiting.

Hoe ZOBONE lyk en inhoud van die verpakking:

'n Wit tot naaswit gevriesdroogde koekie in 'n 5 mL-flessie.

ZOBONE word verpak in 'n 5 mL helder, kleurlose, USP tipe-I buisvormige glasflessie, met 'n 20 mm grys, bromobutiel- Igloo RFS (gereed vir sterilisasie) rubberprop en 20 mm aftrekbare seël met 'n goud-bruin kleur.

Pakgrootte:

1 flessie.

Houer van die registrasiesertifikaat:

Ranbaxy Pharmaceuticals (Pty) Ltd

Lautreweg 14

Stormill, Uitbreiding 1, Roodepoort

Johannesburg 1724

Tel. 012 643 2000

Hierdie inligtingstuk was laas hersien op:

Om toegeken te word.

Registrasienommer:

42/34/0664

Datum van registrasie:

4 Maart 2011

Namibië: NS2 13/34/0190