Applicant : Biomab Innovation (Pty) Ltd
Proprietary name : Eurodron
Dosage form and strength : Concentrate for solution for infusion
Date of submission : 26 April 2024
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APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

EURODRON concentrate for solution for infusion

Zoledronic acid

Read all of this leaflet carefully before you are given EURODRON

- **Keep this leaflet. You may need to read it again.**
- **If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.**

What is in this leaflet

1. What EURODRON is and what it is used for
2. What you need to know before you use EURODRON
3. How to use EURODRON
4. Possible side effects
5. How to store EURODRON
6. Contents of the pack and other information

1. What EURODRON is and what it is used for

Patients with tumours can sometimes have high levels of calcium in their blood (hypercalcaemia), released from bones, making bones likely to break (fracture).

EURODRON is used to treat hypercalcaemia caused by tumours. EURODRON is also used to treat bone damage caused by myeloma (cancer that begins in the white blood cells that produce substances needed to fight infection) or by cancer that began in another part of the body but has spread to the bones.

EURODRON is not an anti-cancer therapy.

2. What you need to know before you use EURODRON

EURODRON 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 EURODRON (see **What EURODRON contains**).

- If you have severe kidney disease.
- If you are pregnant or breastfeeding.

Warnings and Precautions

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

Take special care with EURODRON:

- Ensure that you drink enough liquids before receiving EURODRON in order to prevent dehydration.
- EURODRON may interfere with your kidney function. Consult your doctor if you experience any changes in your kidney function. Take note of changes in the volume of urine you pass or generalised swelling of the hands and feet.
- You should know that EURODRON may cause osteonecrosis of the jaw (a serious condition of the jaw bone), especially if you have dental surgery or treatment while you are using EURODRON. A dentist should examine your teeth and perform any needed treatments, including cleaning, before you start using EURODRON. Be sure to brush your teeth and clean your mouth properly while you are using EURODRON. Talk to your doctor before having any dental treatments while you are receiving EURODRON.
- The long-term use of EURODRON can cause osteonecrosis of the external auditory canal (the ear canal – pathway running from the outer ear to the middle ear). The possible risk factors for this condition includes steroid use (for example prednisone) and

chemotherapy as well as local risk factors such as infection or trauma. If you present with ear symptoms such as chronic ear you should inform your doctor.

- EURODRON may cause severe bone, joint and/or muscle pain. Tell your doctor if you present with these symptoms, because stopping the treatment may bring relieve.
- EURODRON may cause unusual fracture/s of the thigh bone (femur), particularly in patients on long-term treatment. Consult your doctor if you experience any pain, weakness or discomfort in your thigh, hip or groin area as this may be an early indication of a possible fracture of the thigh bone.
- EURODRON may alter the levels of calcium in your body and you may need treatment for those changes. Please tell your doctor if you have low levels of calcium in your blood.

Other medicines and EURODRON

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

The following medicines may interact with EURODRON:

- Medicines known to be harmful to your kidneys (e.g. lisinopril, ramipril, candesartan or valsartan, used to treat blood pressure).
- Certain anti-cancer medications (e.g. cisplatin, carboplatin or methotrexate).
- Corticosteroids (used to treat inflammation or other conditions).
- Aminoglycosides (antibiotic used to treat bacterial infections, e.g. amikacin, gentamicin, kanamycin, neomycin or tobramycin).

EURODRON with food and drink

Drink enough water within a few hours before receiving EURODRON to prevent you from getting dehydrated. Unless your doctor tells you otherwise, you can continue your normal diet.

Pregnancy, breastfeeding and fertility

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

DO NOT use EURODRON if you are breastfeeding.

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

Driving and using machines

EURODRON may impair your ability to drive and use machinery; do take care if you feel dizzy, tired or drowsy while using EURODRON. Do not drive or operate any machinery until you know how EURODRON affects you.

3. How to use EURODRON

You will not be expected to give yourself EURODRON. It will be given to you by a person who is qualified to do so. EURODRON is an injection and will be given to you by your doctor. Your doctor will dilute it with another intravenous solution and give it as a slow infusion into a vein. A lower dose will be given to you if you have mild to moderate problems with your kidneys.

Your doctor will decide when you will be given EURODRON and how often you should receive infusions.

Your doctor may also prescribe or recommend a calcium supplement and a multivitamin containing vitamin D to take during your treatment. You should take these supplements every day as directed by your doctor.

If you receive more EURODRON than you should

Since a health care provider will administer EURODRON he / she will control the dosage.

However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use EURODRON

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

4. Possible side effects

EURODRON can have side effects.

Not all side effects reported for EURODRON are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving EURODRON, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using EURODRON and tell your doctor immediately:

- Swelling of the hands, feet, ankles, face, lips, 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 allergic reaction to EURODRON. You may need urgent medical attention.

Tell your doctor immediately if you notice any of the following:

Less frequent side effects:

- Irregular heart rhythm (atrial fibrillation), slowing of the heartbeat or irregular heartbeat.
- Difficulty breathing, shortness of breath, coughing, wheezing.
- Kidney failure.
- Chest pain.

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

Tell your doctor as soon as possible if you notice any of the following:

Frequent side effects:

- Anaemia, a condition in which the number of red blood cells is decreased.
- Headache.
- Eye infection.
- Nausea and vomiting.
- Loss of appetite.
- Bone, joint and/or muscle pain.
- Change in kidney function.
- Fever and flu-like symptoms.
- Low level of phosphate and calcium in the blood.
- Increase blood creatinine and blood urea (waste products in the body) which is caused by kidney impairment.

Less frequent side effects:

- Abnormal bleeding.
- Increased risk of infections.
- Anxiety, difficulty sleeping, confusion.
- Dizziness.

- Trembling, tingling or numbness of the hands or feet.
- Taste disturbances.
- Drowsiness.
- Seizures.
- Blurred vision.
- Painful redness of the eye.
- Diarrhoea or constipation.
- Stomach pain, indigestion, ulcers of the mouth or lips, dry mouth.
- Increased sweating.
- Muscle cramps.
- Changes in blood pressure.
- Undesirable reactions caused by your immune system.
- Redness and swelling at infusion site, rash and itching.

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

Reporting of side effect

If you get side effects, talk to your doctor. You can also report side effects to SAHPRA via the "6.04 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 EURODRON.

5. How to store EURODRON

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Do not freeze.

- The diluted solution can be stored at 2 to 8 °C and must be administered within 24 hours.
- Do not use 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).

6. Contents of the pack and other information

What EURODRON contains

Each vial with 5 ml concentrate contains 4 mg zoledronic acid as zoledronic acid monohydrate.

The inactive ingredients are: Mannitol, sodium citrate dihydrate, water for injection.

What EURODRON looks like and contents of the pack

- Clear, colourless, cycloolefine, copolymer plastic vial with a grey, type I bromobutyl rubber stopper (20 mm) and sealed with an aluminium seal with a white polypropylene flip-off cap.
- Clear Type I silicon dioxide inner coated glass vials, capped with rubber stoppers and sealed with aluminium cap with flip off seals.
- Clear Type I borosilicate glass vials (20 mm) and sealed with rubber stoppers, type I, bromobutyl, 20 mm injection stopper.
- Packs containing 1, 4 or 10 vials. Not all pack sizes may be marketed.

Holder of Certificate of Registration

Biomab Innovation (Pty) Ltd.

Woodmead Office Park

3 Stirrup Lane

Van Reenans Avenue

Woodmead 2144

Tel: (011) 656 0031

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