Proposed Patient Information Leaflet

The proposed patient information leaflet conforms to **Regulation 10**.

SCHEDULING STATUS:

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

ZOCLASTA 5 mg/100 ml solution for infusion.

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

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

1. WHAT ZOCLASTA CONTAINS:

The active substance is zoledronic acid.

The other ingredients are: mannitol, sodium citrate and water for injection.

2. WHAT ZOCLASTA IS USED FOR

Zoledronic acid belongs to a group of medicines called bisphosphonates.

It is used to:

- treat osteoporosis,
- prevent additional fractures in patients who have recently had a hip fracture
- treat Paget's disease of the bone.

Osteoporosis is a disease where the bones of the body become thinner and weaker and break easily.

Paget's disease of the bone is a disease that affects the process of forming new bone in the body.

3. BEFORE YOU ARE GIVEN ZOCLASTA

You should not be given ZOCLASTA if:

- if you are hypersensitive (allergic) to zoledronic acid or any of the other ingredients of **ZOCLASTA** (see the section explaining what **ZOCLASTA** contains),
- if you have low levels of calcium in your blood (hypocalcaemia),
- if you are pregnant or plan on becoming pregnant,
- if you are breastfeeding,
- if you have a severe kidney problem.
- if you are being treated with other bisphosphonates which contains the same active ingredient as **ZOCLASTA.**
- if you are under the age of 18. The use of **ZOCLASTA** in children and adolescents has not been studied.

If you are uncertain whether any of these apply to you, please discuss this with your doctor or pharmacist before taking **ZOCLASTA**.

Take special care with ZOCLASTA

- if you have a kidney problem, or you used to have one,
- if you notice that you have difficulty urinating, are urinating excessively or notice a change in the colour of your urine whilst being given **ZOCLASTA**,

- if you suffer from a calcium or vitamin D deficiency,
- if you are unable to take daily calcium or vitamin D supplements,
- if you have had some or all of the parathyroid glands in your neck surgically removed,
- if you have had sections of your intestine removed,
- if you are being treated for Paget's disease of the bone as you may develop low levels of calcium in the blood especially within the first 10 days after receiving **ZOCLASTA**. Your doctor may advise you to take vitamin D and calcium tablets. Signs of low blood calcium include muscle spasms, or numbness, or a tingling sensation in the area around the mouth. Contact your doctor if this occurs,
- if you have severe bone or muscle pain whilst being given **ZOCLASTA**,
- if you have or have had cancer,
- if you are taking or have recently taken medicines called corticosteroids (such as prednisone) or medicines used to treat cancer (chemotherapy),
- if you have any problems with your mouth or teeth such as poor dental health or gum disease,
- if you have (or have had) pain, swelling or numbness in your gums, jaw or both, if your jaw feels heavy, or if you have lost a tooth.

Before you receive dental treatment or undergo dental surgery, such as extraction of a tooth, tell your dentist you are receiving treatment with **ZOCLASTA**.

Receiving ZOCLASTA with food and drink

It is important that you stay well hydrated. Make sure you drink enough fluids (at least one or two glasses) before and after treatment with **ZOLCLASTA** as directed by your doctor. This will help to prevent dehydration. On the day that you are treated with **ZOCLASTA** you may eat and drink normally.

Pregnancy and breastfeeding:

You should not be given **ZOCLASTA** if you are pregnant or breastfeeding.

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other health care professional for advice before receiving **ZOCLASTA**.

Driving and using machinery

ZOCLASTA may make you feel dizzy or sleepy and could interfere with your ability to drive safely.

If this happens do not drive or use machines until you feel better.

Using other medicines with ZOCLASTA

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

If you are taking any medicines containing the following:

- aminoglycoside antibiotics, these may be harmful to your kidneys,
- diuretics (“water pills”), these may make you dehydrated.

Consult your doctor, pharmacist or other healthcare professional for advice if you are unsure.

4. HOW ZOCLASTA IS GIVEN:

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

Carefully follow all instructions given to you by your doctor, nurse or pharmacist.

Follow all instructions given to you by your doctor. On the day of treatment with **ZOCLASTA** you should eat and drink normally. Follow your doctor’s instructions on how much water to drink as this will stop you from becoming dehydrated.

You will not be expected to give yourself **ZOCLASTA** It will be given to you by a person who is qualified to do so.

- the usual dose is 5 mg given as one infusion per year into a vein by your doctor or nurse,
- the infusion lasts 15 minutes,
- it is important that you take calcium and vitamin D supplements as directed by your doctor.

ZOCLASTA works for one year so you will need another dose after one year. Your doctor will let you know when to return for your next dose.

If you have the impression that **ZOCLASTA** is too strong or too weak, tell your doctor or pharmacist.

If you receive more ZOCLASTA than you should:

Since a healthcare professional will administer **ZOCLASTA**, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If a dose of ZOCLASTA is missed:

Contact your doctor or hospital as soon as possible to re-schedule your appointment.

Before stopping ZOCLASTA therapy:

If you stop taking **ZOCLASTA** your original symptoms may come back. If you are considering stopping **ZOCLASTA** treatment, discuss this with your doctor. Your doctor will advise you and decide how long you need to be treated with **ZOCLASTA**.

5. POSSIBLE SIDE EFFECTS

ZOCLASTA may cause side effects.

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

If you receive **ZOCLASTA** for the first time, you may experience side effects such as flu-like symptoms, fever (high temperature) and chills, pain in the muscles and joints and headaches. These symptoms are usually mild to moderate and may go away after three days. Your doctor may recommend a mild pain reliever such as paracetamol or ibuprofen. The chances of experiencing these side effects will also decrease with subsequent annual doses of **ZOCLASTA**.

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

- swelling of the face, lips, tongue, throat or other parts of the body,
- having difficulty breathing with or without swelling of the throat and face,
- shortness of breath, wheezing or trouble breathing,
- severe itching of the skin.

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

Tell your dentist immediately if you experience:

- pain in the mouth, teeth and jaw, swelling or sores inside the mouth, 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).

Contact a doctor as soon as possible:

Less frequent:

- anaemia (a decrease in your red blood cells). You may feel very tired or look pale,
- severe pain in the eye or have difficulty with seeing,
- effects on how your kidneys work, especially if you have kidney problems or heart failure.

Tell your doctor if you have difficulty urinating, are urinating excessively or if you notice that your urine has changed colour.

Tell your doctor if you notice any of the following:

Frequent

- headache, feeling dizzy,
- feeling “sick” (nausea), vomiting, diarrhoea,
- pain in the joints, leg (femur) and muscles,
- fever (high temperature), chills, feeling tired and weak, pain, a general feeling of being unwell.

Less frequent:

- an increase in infections such as a “cold” or having a runny nose,
- decrease in appetite,
- difficulty in falling off to sleep or staying asleep,
- feeling tired and uninterested (lethargy), drowsiness,
- tingling sensation or numbness (paraesthesia), trembling (tremors), fainting,
- feeling dizzy or a spinning sensation (vertigo),
- increase in blood pressure where you may feel dizzy, have a headache, blurred vision or chest pain; flushing,
- cough, shortness of breath or difficulty breathing,
- upset stomach, pain in the stomach area, heartburn, dry mouth, constipation,
- rashes, excessive sweating, itching and reddening of the skin,

- feeling of weakness in the muscles, muscle spasms, stiffness in the muscles, bones and/ or joints,
- swelling of the extremities (hands and feet), thirst, non-cardiac chest pain,
- change in the rhythm of your heart beat (atrial fibrillation),
- kidney disorders (e.g. decreased urine output) may occur. Your doctor should do a blood test to check your kidney function.

Frequency unknown:

- low blood pressure where you may feel faint, confused, have blurred vision and your heart may suddenly beat fast.
- thrombophlebitis (your leg may be swollen and red and you may experience pain).

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

6. STORING AND DISPOSING OF ZOCLASTA

Your doctor, nurse or pharmacist knows how to store **ZOCLASTA**. The healthcare professional who is administering **ZOCLASTA** to you will make sure that the medicine is not used after the expiry date printed on the bag and that it is given to as soon as the seal is broken. They will also visually inspect the solution before giving it to you and only clear solution without particles will be used.

7. PRESENTATION OF ZOCLASTA

ZOCLASTA 5 mg/100 ml solution for infusion is supplied in a clear 100 ml silicone dioxide inner coated glass vial capped with a bromobutyl rubber stopper and sealed with an aluminium polypropylene flip off seal. **ZOCLASTA** is supplied in packs containing one bottle and multipacks

comprising three or six packs, each containing one bottle and a vented infusion set. Not all pack sizes may be marketed.

8. IDENTIFICATION OF ZOCLASTA

ZOCLASTA is a sterile, clear and colourless solution. The solution is free from particles.

9. REGISTRATION NUMBER

49/34/1081

10. NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Camox Pharmaceuticals (Pty) Ltd

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11. DATE OF PUBLICATION

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