PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PROPRIETARY NAME AND DOSAGE FORM:

ACLASTA 5 mg/100 mℓ solution for infusion

Read all of this leaflet carefully before you are given ACLASTA:

- 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.
- ACLASTA 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 ACLASTA CONTAINS

The *active substance* of ACLASTA is zoledronic acid.

The *other ingredients* are mannitol, sodium citrate and water for injections.

2. WHAT ACLASTA IS AND WHAT IT IS USED FOR

ACLASTA is given as a single infusion into a vein by a doctor or nurse. It belongs to a group of medicines called *bisphosphonates*, and is used to:

- treat osteoporosis in postmenopausal women.
- treat osteoporosis in men.
- prevent additional clinical fractures in postmenopausal women who have recently had a hip fracture due to low level trauma/injury.
- treat osteoporosis in men and women caused by treatment with steroid medicines

such as prednisone.

- treat Paget's disease of the bone.

For osteoporosis and the prevention of additional fractures, ACLASTA works for one year and you will need the next dose after one year. For Paget's disease, ACLASTA may work for longer than one year, and your doctor will let you know if you need to be treated again.

3. BEFORE ACLASTA IS ADMINISTERED TO YOU

Carefully follow all instructions given to you by your doctor. On the day of treatment with ACLASTA you should eat and drink normally. Follow you doctor's instructions on how much water to drink; this is important as it will help to prevent you becoming dehydrated.

You should not be given ACLASTA:

- If you are allergic (hypersensitive) to zoledronic acid or any of the other ingredients of ACLASTA.
- If you have hypocalcaemia (this means that the levels of calcium in your blood are too low).
- If you are pregnant or plan to become pregnant.
- If you are breastfeeding.
- If you have severe impairment of renal function (creatinine clearance of < 35 mℓ/min).

Take special care with ACLASTA:

- If you are being treated with other bisphosphonates, which contains the same active ingredient as in ACLASTA.
- If you have, or used to have, a kidney problem.
- If you suffer from calcium or vitamin D deficiency.
- If you are unable to take daily calcium and vitamin D supplements.
- If you had some or all of the parathyroid glands or thyroid in your neck surgically

removed.

- If you had sections of your intestine removed.
- If you had or have pain, swelling or numbness of the jaw or a loosening of the tooth.
- If you are under dental treatment or will undergo dental surgery, such as a tooth extraction, tell your dentist that you are being treated with ACLASTA.

Other medicines and ACLASTA:

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including any you have bought without a prescription.

It is especially important for your doctor to know if you are taking any medicines known to be harmful to your kidneys.

ACLASTA with food and drink:

Make sure you drink enough fluids (at least one or two glasses) before and after the treatment with ACLASTA, as directed by your doctor. This will help to prevent dehydration. You may eat normally on the day you are treated with ACLASTA.

Pregnancy and breastfeeding:

You should not be given ACLASTA if you are pregnant or plan to become pregnant.

Ask your doctor or pharmacist for advice before ACLASTA is administered to you.

You should not be given ACLASTA if you are breastfeeding.

Older patients (age 65 years and over):

ACLASTA can be given to older people.

Children and adolescents:

ACLASTA is not recommended for anyone under 18 years of age. The use of ACLASTA in children and adolescents has not yet been studied.

4. HOW ACLASTA IS ADMINISTERED TO YOU

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

Your doctor will tell you how long your treatment with ACLASTA will last.

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

Osteoporosis in men and women and Prevention of clinical fractures after hip fracture in postmenopausal women:

The usual dose is 5 mg given as one infusion per year into a vein by your doctor or nurse.

The infusion will take at least 15 minutes.

Since most people do not get enough calcium and vitamin D in their diet, it is important to take calcium and vitamin D supplements (for example tablets) as directed by your doctor.

For osteoporosis and prevention of clinical fractures ACLASTA works for one year so you will need another dose after one year.

Paget's disease:

The usual dose is 5 mg, given to you as one single infusion into a vein by your doctor or nurse. The infusion will take at least 15 minutes. Because ACLASTA works for a long time, you may not need another dose of ACLASTA for a year or longer. Your doctor will let you know if you need to be treated again.

Your doctor might advise you to take calcium and vitamin D supplements (e.g. tablets) for at least the first ten days after being given ACLASTA. It is important that you follow this advice carefully in order to reduce the risk of hypocalcaemia (too low blood calcium) in the period

after infusion. Your doctor will inform you regarding the symptoms associated with hypocalcaemia.

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

IF A DOSE OF ACLASTA IS MISSED:

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

BEFORE STOPPING ACLASTA THERAPY:

If you are considering stopping ACLASTA treatment, please go to your next appointment and discuss this with your doctor. Your doctor will advise you and decide how long you should be treated with ACLASTA.

5. POSSIBLE SIDE EFFECTS

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

Side effects related to the first infusion are very common (occurring in more than 40% of patients) but are less common following subsequent infusions. The majority of the side effects, such as fever and chills, pain in the muscles or joints, and headache, occur within the first three days following the dose of ACLASTA. The symptoms are usually mild to moderate and go away within three days of starting. Your doctor can recommend a mild pain reliever such as ibuprofen or paracetamol to make you feel more comfortable. The chance of experiencing these side effects decreases with subsequent doses of ACLASTA.

Skin reactions such as redness, swelling and/or pain at the infusion site may occur. ACLASTA may cause swelling, redness, pain and itching to the eyes or eye sensitivity to light, pain in the mouth, teeth and jaw, swelling of 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). **Tell your dentist immediately** if you experience such symptoms.

Irregular heart rhythm (atrial fibrillation) has been seen in patients receiving ACLASTA for postmenopausal osteoporosis. It is currently unclear whether ACLASTA causes this irregular heart rhythm but you should report it to your doctor if you experience such symptoms after you have received ACLASTA.

Kidney disorders (e.g. decreased urine output) may occur. Your doctor may do a blood test to check your kidney function before each dose of ACLASTA. It is important for you to drink at least 2 glasses of fluid (such as water), within a few hours before receiving ACLASTA, as directed by your healthcare provider.

Treatment of postmenopausal osteoporosis, osteoporosis in men and Paget's disease of bone, Prevention of clinical fractures after hip fracture, Treatment of glucocorticoid-induced osteoporosis.

Very common side effect *(affecting 10 or more in every 100 patients)*:

Fever.

Common side effects *(affecting less than 10 in every 100 patients)*:

Headache, dizziness, sickness, vomiting, diarrhoea, muscle pain, joint pain, bone pain, back pain, pain in your hands and/or feet, flu-like symptoms (e.g. tiredness, chills, joint and muscle pain), chills, being tired and uninterested, weakness, pain, feeling unwell.

In addition in patients with Paget's disease: symptoms due to low blood calcium, such as muscle spasms, or numbness, or a tingling sensation especially in the area around the mouth, shortness of breath.

Uncommon side effects *(affecting less than 1 in every 100 patients)*:

Flu, upper respiratory tract infections, decreased red cell count, loss of appetite, sleeplessness, reduced alertness and awareness, tingling sensation or numbness, drowsiness, trembling, temporary loss of consciousness, swelling or infection of the membrane lining the eyelids, eye infection, irritation and inflammation with pain and redness, spinning sensation, increased blood pressure, flushing, cough, shortness of breath, upset stomach, abdominal pain, constipation, dry mouth, heartburn, skin rash, excessive sweating, itching, skin reddening, neck pain, stiffness in muscles, bones and/or joints, joint swelling, muscle spasms, shoulder pain, pain in your chest muscles and rib cage, joint inflammation, muscular weakness, abnormal kidney test results, kidney failure, abnormal frequent urination, swelling of hands, ankles or feet, thirst, acute phase reaction (the body's immune response to ACLASTA e.g. muscle pain and fever), non-cardiac chest pain.

Rare side effects *(affecting less than 1 in every 1,000 patients)*:

Swelling mainly of the face and throat, kidney disorder (e.g. decreased urine output).

Very rare side effects *(affecting less than 1 in every 10,000 patients)*:

Severe allergic reaction including dizziness and difficulty breathing, dehydration secondary to post-dose symptoms such as fever, vomiting and diarrhoea; decreased blood pressure; pain in the mouth, teeth and jaw, swelling of sores inside the mouth, numbness or a feeling of heaviness in the jaw, or loosening of a tooth.

Additional observed side effects:

Disturbed sense of taste, toothache, stomach pain, sensation of forceful and/or irregular heart beat, skin reaction at the infusion site, eye sensitivity to light.

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist, or nurse. 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 ACLASTA. Suspected side effects can also be reported directly to the Holder of the Certificate of Registration (HCR) via the link: https://pvi1j.solutions.iqvia.com or the e-mail address, adverse.event.sac@sandoz.com.

6. STORING AND DISPOSING OF ACLASTA

Your doctor, nurse or pharmacist knows how to store ACLASTA properly.
Store ACLASTA at or below 30°C. Keep the original packaging unchanged and sealed until a doctor or a nurse administers ACLASTA.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

7. PRESENTATION OF ACLASTA

ACLASTA 5 mg/100 mℓ solution for infusion comes in 100 mℓ plastic vials, as a ready-to-use solution for infusion. ACLASTA is supplied in packs containing one vial and multipacks of three or six individually packed vials. Not all pack sizes may be marketed in South Africa.

8. IDENTIFICATION OF ACLASTA

The infusion is a clear and colourless aqueous solution.

9. REGISTRATION NUMBER

A39/34/0575

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Sandoz SA (Pty) Ltd[1]

Waterfall 5-lr

Magwa Crescent West

Waterfall City

Jukskei View

2090

11. DATE OF PUBLICATION

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[1]Company Reg. No.: 1990/001979/07

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