

PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

BONAZOLL 5 mg/100 mL solution for infusion

Zoledronic acid

Contains sugar: Mannitol 4,950 g/100 mL

Contains sodium: Sodium citrate 30 mg/100 mL

Read all this leaflet carefully before you start taking BONAZOLL 5

- 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 **BONAZOLL 5** is and what it is used for
2. What you need to know before you are given **BONAZOLL 5**
3. How **BONAZOLL 5** will be administered
4. Possible side effects

Date of Leaflet: 29 August 2023



5. How **BONAZOLL 5** is stored

6. Contents of the pack and other information

1. What BONAZOLL 5 is and what is it used for:

BONAZOLL 5 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 post-menopausal 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, **BONAZOLL 5** works for one year and you will need the next dose after one year. For Paget's disease, **BONAZOLL 5** may work for longer than one year, and your doctor will let you know if you need to be treated again.

2. What you need to know before you are given BONAZOLL 5:

Carefully follow all instructions given to you by your doctor. On the day of treatment with **BONAZOLL 5** you should eat and drink normally. Follow your 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 BONAZOLL 5:

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- If you are allergic (hypersensitive) to zoledronic acid, other bisphosphonates, or any of the other ingredients of **BONAZOLL 5** listed in section 6.
 - 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 kidney disease

Warnings and precautions

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

- are being treated with other products containing the same active substance zoledronic acid as in **BONAZOLL 5**. Other products containing the active substance zoledronic acid are used in adult patients with certain types of cancer to prevent bone complications or to reduce the amount of calcium)
- have a kidney problem or used to have one.
- suffer from a calcium or Vitamin D deficiency.
- have had some or all of the parathyroid glands in your neck surgically removed.
- have had sections of your intestine removed.

A side effect called osteonecrosis of the jaw (ONJ) (bone damage in the jaw) has been reported in the post-marketing setting in patients receiving zoledronic acid for osteoporosis. ONJ can also occur after stopping treatment.



It is important to try and prevent ONJ developing as it is a painful condition that can be difficult to treat. In order to reduce the risk of developing osteonecrosis of the jaw, there are some precautions you should take.

Before receiving **BONAZOLL 5** treatment, tell your doctor if you:

- have any problems with your mouth or teeth such as poor dental health, gum disease, or a planned tooth extraction.
- do not receive routine dental care or have not had a dental check-up for a long time.
- are a smoker (as this may increase the risk of dental problems)
- have previously been treated with a bisphosphonate (used to treat or prevent bone disorders)
- are taking medicines called corticosteroids (such as prednisolone or dexamethasone)
- have cancer.

Your doctor may ask you to undergo a dental examination before you start treatment with **BONAZOLL 5**.

While being treated with **BONAZOLL 5**, you should maintain good oral hygiene (including regular teeth brushing) and receive routine dental check-ups. If you wear dentures you should make sure these fit properly. If you are under dental treatment or are due to undergo dental surgery (e.g. tooth extractions), inform your doctor about your dental treatment and tell your dentist you are being treated with **BONAZOLL 5**. Contact your doctor and dentist immediately if you experience any

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Product Proprietary Name: BONAZOLL 5

Dosage Form & Strength: Zoledronic acid 5mg/100mL solution for infusion

CTD, Module 1

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 osteonecrosis of the jaw.

Monitoring test

Your doctor should do a blood test to check your kidney function (levels of creatinine) before each dose of **BONAZOLL 5**. It is important for you to drink at least 2 glasses of fluid (such as water), within a few hours before receiving **BONAZOLL 5**, as directed by your healthcare provider.

Children and adolescents:

BONAZOLL 5 is not recommended for anyone under 18 years of age.

Other medicines and BONAZOLL 5:

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary and traditional medicines).

It is important for your doctor to know all the medicines you are taking, especially if you are taking any medicines known to be harmful to your kidneys (e.g. aminoglycosides) or diuretics ("water pills") that may cause dehydration.

Pregnancy and breastfeeding and fertility:

You must not be given **BONAZOLL 5** if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby.

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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 taking this medicine.

Driving and using machines:

If you feel dizzy or sleepy during **BONAZOLL 5** treatment, do not drive or use machines until you feel better.

It is not always possible to predict to what extent **BONAZOLL 5** may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which **ONLAST** affects you.

Sodium: This medicine contains less than 1 mmol sodium (23 mg) per 100 ml vial, that is to say essentially 'sodium-free'.

3. How BONAZOLL 5 will be administered:

You will not be expected to give yourself **BONAZOLL 5**. 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 **BONAZOLL 5** will last.

BONAZOLL 5 with food, drink, and alcohol:

Make sure you drink enough fluids (at least one or two glasses) before and after the treatment with **BONAZOLL 5**, as directed by your doctor. This will help to prevent dehydration.

You may eat normally on the day you are treated with **BONAZOLL 5**.

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The usual dose is:

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 **BONAZOLL 5** 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

BONAZOLL 5 works for a long time, you may not need another dose of

BONAZOLL 5 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 **BONAZOLL 5**. 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.

If you are administered more BONAZOLL 5 than you should:

Since a healthcare provider will administer **BONAZOLL 5**, he/she will control

the dosage, however, in the event of overdosage your doctor will manage it.

If administration of a dose of BONAZOLL 5 is forgotten:

Since a health care provider will administer **BONAZOLL 5**, it is unlikely that

the dose will be missed.

If you stop BONAZOLL 5 administration

If you are considering stopping **BONAZOLL 5** 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 **BONAZOLL 5**.

4. Possible side effects

BONAZOLL 5 can have side effects.

Not all side effects reported for **BONAZOLL 5** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects

while taking **BONAZOLL 5**, please consult your health care provider for

advice.

If any of the following happens, administration of BONAZOLL 5 should be stopped, your doctor should be informed or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat
- Difficulty breathing
- Rash or itchy skin

These are all very serious side effects. If you have them, you may have had a serious reaction to **BONAZOLL 5**. You may need urgent medical attention or hospitalisation.

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

- irregular heart rhythm (atrial fibrillation)
- swelling, redness, pain and itching to the eyes or eye sensitivity to light.
- ear pain, discharge from the ear, and/or an ear infection. These could be signs of bone damage in the ear.
- pain in the mouth and/or jaw
- swelling, non-healing or discharging sores in the mouth or jaw
- numbness or a feeling of heaviness in the jaw or loosening of a tooth.
- kidney disorders (e.g. decreased or increased urine output)
- muscle spasms, numbness, cramps, stiffness or seizures (these may be signs of low calcium levels)

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- dizziness or light-headedness, headache, tiredness, dry mouth, lips and eyes, passing small amounts of urine infrequently -these may be signs that you are dehydrated.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- fever
- headache
- dizziness
- sickness
- vomiting
- diarrhoea
- pain in the muscles
- pain in the bones and/or joints
- pain in the back, arms or legs
- flu-like symptoms (e.g. tiredness, chills, joint and muscle pain)
- chills
- feeling of tiredness and lack of interest
- weakness
- pain
- feeling unwell
- swelling and/or pain at the infusion site.

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- 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 have been reported.

Less frequent side effects:

- runny or stuffy nose, sneezing, coughing, sore or scratchy throat, watery or itchy eyes, headache, tiredness, body aches. (these may be signs of influenza or an upper respiratory tract infection)
- fatigue, weakness, paleness (may be signs that you are anaemic)
- loss of appetite
- sleeplessness
- sleepiness which may include reduced alertness and awareness
- tingling sensation or numbness
- trembling
- temporary loss of consciousness (fainting)
- eye infection or irritation or 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
- itchy skin
- skin reddening
- neck pain
- stiffness in muscles, bones and/or joints
- joint swelling or inflammation
- muscle spasms or weakness
- shoulder pain
- pain in your chest muscles and rib cage
- abnormal kidney test results
- thirst
- toothache
- taste disturbances.
- low levels of phosphate in the blood – you may experience muscle pain or weakness, confusion, irritability.
- unusual fracture of the thigh bone particularly in patients on long-term treatment for osteoporosis may occur rarely.

Frequency unknown:

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- decreased blood pressure

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

Reporting of side effects

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the “6.04 Adverse Drug Reactions Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.or.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of **BONAZOLL 5**.

5. How to store BONAZOLL 5

Your doctor, nurse or pharmacist knows how to store **BONAZOLL 5** properly.

Store at or below 25 °C. Keep product in outer container until required for use.

Do not use this medicine after the expiry date which is stated on the vial label and carton.

Reconstituted and Infusion Solutions: The product should be used immediately. When prepared as directed, chemical and physical in-use stability of reconstituted and infusion solutions of zoledronic acid were demonstrated for 24 hours at refrigerated temperature. This medicine is for

single use only; any unused solution must be disposed of in accordance with local requirement.

STORE ALL MEDICINE OUT OF REACH OF CHILDREN

6. Contents of the pack and other information

What **BONAZOLL 5** contains:

Active ingredient: Zoledronic acid

Other excipients: mannitol, sodium citrate

What BONAZOLL 5 looks like and contents of the pack

BONAZOLL 5 mg/100 mL solution for infusion is a clear, colourless, sterile solution.

BONAZOLL 5mg/100 mL is packaged in a clear type II glass vial capped with a type I bromobutyl rubber stopper and sealed with an aluminum polypropylene flip off seal. The vial is packed into a carton box along with the patient information Leaflet(s) (PIL).

Holder of Certificate of Registration

Innovata Pharmaceuticals

Crownwood Office Park

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Ormonde

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Dosage Form & Strength: Zoledronic acid 5mg/100mL solution for infusion

CTD, Module 1

Johannesburg

2091

South Africa

This leaflet was revised in

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Access to the corresponding Professional information.

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**A copy of the professional Information is contained in the packaging of
BONAZOLL 5**

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