SCHEDULING STATUS
S4

Bondronat® 50, film-coated tablets
Ibandronic acid
Contains sugar: Lactose monohydrate 92,75 mg per tablet

Read all of the leaflet carefully before you start taking Bondronat 50
- 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.
- Bondronat 50 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 Bondronat 50 is and what it is used for
2. What you need to know before you take Bondronat 50
3. How to take Bondronat 50
4. Possible side effects
5. How to store Bondronat 50
6. Contents of the pack and other information

1. What Bondronat 50 is and what it is used for
The active substance of Bondronat 50, ibandronic acid, belongs to the group of medicines known as bisphosphonates. It inhibits increased loss of calcium from the bones (bone resorption), and slows or prevents the attachment, spread and growth of cancer cells within bone.

Bondronat 50 is indicated in patients with breast cancer and bone metastases for the prevention of skeletal complications requiring radiotherapy.

2. What you need to know before you take Bondronat 50
Do not take Bondronat 50
- If you are hypersensitive (allergic) to ibandronic acid or any of the other ingredients of Bondronat 50 listed in section 6.
- If you have certain problems with your oesophagus (the tube connecting your mouth with your stomach) such as narrowing or difficulty swallowing.
- If you can't stand or sit upright for at least one hour (60 minutes) at a time.
- If you have, or had in the past, low blood calcium. Please consult your doctor.
- If you're pregnant or breast feeding.
- Bondronat 50 should not be used in children. The safety and efficacy of Bondronat in children and adolescents below the age of 18 years have not been established.

Warnings and precautions
A side effect called osteonecrosis of the jaw (ONJ) (bone damage in the jaw) has been reported very rarely in the post marketing setting in patients receiving Bondronat for cancer-related conditions.

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.

Tell your doctor or health care provider before you start taking Bondronat 50 if :
- you have any problems with your mouth or teeth such as poor dental health, gum disease,

or a planned tooth extraction.
- you don't receive routine dental care or have not had a dental check up for a long time.
- you are a smoker (as this may increase the risk of dental problems).
- you have previously been treated with a bisphosphonate (used to treat or prevent bone disorders).
- you are taking medicines called corticosteroids (such as prednisolone or dexamethasone).
- you have cancer.

Your doctor may ask you to undergo a dental examination before starting treatment with Bondronat 50.

While being treated, 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 will undergo dental surgery (e.g. tooth extractions), inform your doctor about your dental treatment and tell your dentist that you are being treated with Bondronat 50.

Contact your doctor and dentist immediately if you experience any problems with your mouth or teeth such as loose teeth, pain or swelling, non-healing of sores or discharge, as these could be signs of osteonecrosis of the jaw.

Atypical fractures of the long bones, such as in the forearm bone (ulna) and the shinbone (tibia), have also been reported in patients receiving long-term bisphosphonate therapy. These fractures occur after minimal, or no trauma and some patients experience pain in the area of the fracture prior to presenting with a completed fracture.

Take special care with Bondronat 50
You should tell your doctor if you know or believe that you may have the following:
- hypersensitivity to other bisphosphonates.
- low blood calcium levels.
- other disturbances of mineral metabolism (such as vitamin D deficiency).
- kidney disease (renal insufficiency i.e. creatinine clearance < 30 mℓ/min).
  or when
- you have had problems in the past with your oesophagus (the tube that connects your mouth to your stomach).
- you become aware of any signs or symptoms suggesting a possible reaction of the oesophagus (this may include: pain in the chest, heartburn, difficult swallowing, pain after swallowing drink andIor food). If you develop these symptoms, stop taking Bondronat 50 and speak to your doctor without delay.
- you are also taking non-steroidal anti-inflammatory drugs (NSAIDs), since both types of medicinal products (NSAIDs and bisphosphonates) may cause irritation to the stomach and intestine.
- you have severe jaw pain.

During treatment your blood may be monitored to ensure that you are receiving the correct dose of Bondronat 50.
If you have a new pain, weakness or a feeling of discomfort in your thigh, hip or groin. You may have early signs of a possible unusual fracture of the thigh bone.

Bondronat 50 can also affect other parts of your face including your ear. This can be aggravated if you have chronic ear infections or if you use cotton-buds.

Other medicines and Bondronat 50
Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed or taking supplements containing calcium, magnesium, iron and aluminium.

No interaction was observed when Bondronat 50 was administered together with tamoxifen, or melphalan/prednisolone.

When administered with H_2-antagonists or other medicines that increase gastric pH Bondronat 50 absorption may be slightly increased but no dose adjustment is needed.

Caution is advised when Bondronat 50 is administered with aminoglycoside antibiotics since both medicines can lower serum calcium levels for prolonged periods.

Caution should also be paid to the possible existence of simultaneous hypomagnesaemia (reduced magnesium levels).

After taking your Bondronat 50 tablet, wait for 30 to 60 minutes before taking any other medication of the day, including indigestion tablets/medicine, calcium supplements and vitamins.

Bondronat 50 with food and drink
Your Bondronat 50 tablets should be taken after an overnight fast (at least 6 hours) and before the first food or drink of the day.

Medications and supplements (including calcium) should similarly be avoided prior to taking Bondronat 50 tablets. Fasting, including avoiding other medication and supplements should be continued for at least 30 to 60 minutes after taking the tablet. Plain water may be taken at any time during the course of Bondronat 50 treatment.

Pregnancy and breastfeeding
Bondronat 50 should not be used during pregnancy and lactation. There are no adequate data from the use of ibandronic acid in pregnant women.

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 healthcare provider for advice before taking Bondronat 50.

Driving and using machines
You can drive and use machines as it is expected that Bondronat 50 has no or negligible effect on your ability to drive and use machines. Talk to your doctor first if you want to drive, use machines or tools.

Bondronat 50 contains lactose monohydrate
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Bondronat 50.

Bondronat 50 contains Macrogol
Macrogol may cause stomach upset and diarrhoea.

3. How to take Bondronat 50
Do not share medicines prescribed for you with any other person.

Always take Bondronat 50 exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacis if you are not sure.

The usual dose of Bondronat 50 is one 50 mg film-coated tablet per day. If you have severe kidney problems, your doctor may reduce your dose to one tablet per week.

To reduce possible irritation, it is important that you follow the instructions below:
- BEFORE taking your first food, drink or other medicinal products of the day, take your Bondronat 50 tablet with a full glass of plain water only (180 to 240 mℓ). Do not take your tablet with any drink other than plain water. Please note that some mineral waters may have a higher concentration of calcium and therefore should also not be used.
- Do not chew, suck or allow the tablet to dissolve in your mouth as it may lead to ulceration in the mouth and throat.
- After taking your Bondronat 50 tablet, wait for 30 to 60 minutes before taking your first food, beverage, or other medication of the day.
- You should remain in an upright (sitting or standing) position while taking Bondronat 50 tablets and remain upright for 60 minutes after taking your tablet
- It is important to continue taking Bondronat 50 for as long as your doctor prescribes the medicine. Bondronat 50 can help with your condition only if you continue to take the tablets.

If you take more Bondronat 50 than you should
If you had taken too many tablets by mistake, drink a full glass of milk and contact your doctor immediately. Do not make yourself vomit and do not lie down.
Do not share medicines prescribed for you with others. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre

If you forget to take Bondronat 50
If you miss a dose do not take an extra tablet on the same day to make up for missed doses. Return to taking one tablet per day the following day as usual.

4. Possible side effects
Bondronat 50 can cause side effects.

Not all side effects reported for Bondronat 50 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Bondronat 50, please consult your health care provider for advice.

If any of the following happens, 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,
- severe adverse skin reactions: sores, blistering and peeling of the skin.

These are all very serious side effects. If you have them, you may have had a serious reaction to Bondronat 50. 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:
- persistent eye pain and inflammation
- new pain, weakness or discomfort in your thigh, hip or groin. You may have early signs of a possible unusual fracture of the thigh bone
- pain or sore in your mouth or jaw. You may have early signs of severe jaw problems (necrosis (dead bone tissue) in the jawbone)
- ear pain, discharge from the ear, and/or an ear infection. These could be signs of bone damage in the ear
- worsening of asthma attacks

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

Tell your doctor if you notice any of the following:
Common side effects (may affect up to 1 in 10 people):
- tummy pain, indigestion
- low calcium levels in your blood
- tiredness/weakness

Uncommon side effects (may affect less than 1 in 100 people):
- anaemia (bloodlessness)
- itching or tingling (paraesthesia)
- strange taste in your mouth
- feeling sick, heartburn and discomfort in swallowing (inflammation of your gullet/food pipe)
- dry mouth
- difficulty swallowing
- constipation
- diarrhoea
- severe stomach pain. This could be a sign of an ulcer of the first section of the bowel (duodenum) that is bleeding, or that your stomach is inflamed (gastritis)
- chest pain
- flu-like symptoms, feeling generally unwell or in pain
- High levels of urea or high levels of parathyroid hormone in your blood

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

Reporting of side effects
If you get side effects, talk to your doctor, nurse or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of Bondronat 50.
For reporting of side effects directly to Adcock Ingram Limited, contact +27 11 635 0134 or email Adcock.aereports@adcock.com.

5. How to store Bondronat 50
- Store at or below 30 ºC.
- Store all medicines out of reach of children.
- Do not put your tablets into another container; store in the original package; protect from moisture. Do not remove your tablets from their pack until you are ready to take them.
- Do not use Bondronat 50 after the expiry date stated on the pack.
- Return unused or expired medicines to your pharmacist for safe disposal.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information
What Bondronat 50 contains
The active substance is ibandronic acid. Each tablet contains 50 mg of ibandronic acid, (as ibandronic sodium monohydrate).
The other ingredients are:
- Tablet core: colloidal anhydrous silica, crospovidone, lactose monohydrate, microcrystalline cellulose, povidone k25, stearic acid 95
- Tablet coat: hypromellose, macrogol 6 000, talc, titanium dioxide

What Bondronat 50 looks like and contents of the pack
Bondronat 50 is a white to off-white coloured, oblong shaped, film-coated tablet, engraved L2 on one side and IT on the other side.

Bondronat 50 is available in pack sizes of 28 and 84 film-coated tablets in transparent PVC/aluminium or aluminium/aluminium blister strips.

Not all pack sizes may be marketed.

Holder of Certificate of Registration
Adcock Ingram Limited
1 New Road
Erand Gardens
Midrand, 1685
Customer Care: 0860 ADCOCK / 232625

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