SCHEDULING STATUS:
S4

BONDRONAT® 2 mg/2 mℓ, injection
BONDRONAT® 6 mg/6 mℓ, injection
Ibandronic acid
Sugar free

Read all of the leaflet carefully before you are given BONDRONAT
- 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** 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 is and what it is used for
BONDRONAT contains the active substance ibandronic acid. This belongs to a group of medicines called bisphosphonates.

BONDRONAT is used in adults to:
- Treat high levels of calcium in the blood caused by tumours (tumour-induced hypercalcaemia).
- Prevent bone problems in patients with breast cancer that has spread to the bones (bone metastases), such as:
  - bone fractures
  - the need for surgery or radiotherapy to the bones.

BONDRONAT works by reducing the loss of calcium from your bones. This helps to keep them strong and reduce the risk of complications.

2. What you need to know before you receive BONDRONAT
BONDRONAT should not be administered to you:
- If you are hypersensitive (allergic) to ibandronic acid or any of the other ingredients of **BONDRONAT** listed in section 6.
- If you have low levels of calcium in your blood (hypocalcaemia).
- If you are pregnant or breastfeeding (see section on Pregnancy and breastfeeding).

Warnings and precautions

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

- you have had an allergic reaction to other bisphosphonates (used to treat or prevent bone disorders)
- have low blood calcium
- you have any other mineral imbalances, (such as vitamin D deficiency)
- you have had other medicines to treat or prevent bone conditions (especially bisphosphonates)
- you have cancer.
- you are a smoker (smoking increases the risk of dental problems and jawbone damage)
- you are taking medicines called corticosteroids (such as prednisolone or dexamethasone)
- you have problems with your mouth or teeth (e.g., gum disease, poor dental health, or a planned tooth extraction)
- you do not receive routine dental care or have not had a dental check-up for a long time
- you have kidney problems
- you have heart problems, and your doctor has advised you to limit fluid intake

Take special care with BONDRONAT if any of the following apply to you:

Severe allergic reactions (Anaphylaxis)

BONDRONAT can sometimes cause serious allergic reactions, including anaphylactic shock, which can be life-threatening.

You should immediately alert your doctor or other healthcare professional if you have any of the following:

- trouble breathing or shortness of breath
- tightness in your chest or throat
- swelling of your tongue, lips, face, or throat
- dizziness, fainting
- rash, redness, or itching
- nausea or vomiting

Problems with your jaw or mouth (Osteonecrosis of the jaw – ONJ)

A rare but serious condition called osteonecrosis of the jaw (ONJ) has been reported in patients receiving **BONDRONAT**, especially those with cancer.

To lower your risk:

- Your doctor may refer you for a dental check-up before you start treatment.
- Keep your mouth clean and brush your teeth regularly.
- Go for regular dental check-ups.
- Make sure dentures fit properly.
- Tell your dentist you are being treated with **BONDRONAT** before having any dental work.
- Tell your doctor or dentist straight away if you notice:
  - loose teeth
  - pain, swelling, or non-healing sores in your mouth
  - any discharge from your mouth or gums

Unusual bone fractures

Rare fractures of the thigh, arm, or shin bones can happen with little or no injury in patients taking **BONDRONAT** for a long time.

- If you get new or unusual pain in your thigh, hip, groin, or lower leg, tell your doctor immediately – it could be an early sign of a fracture.
- Patients using walking aids may be at higher risk for certain types of fractures (e.g., in the forearm).

Bone damage in the ear (Osteonecrosis of the external auditory canal)

In very rare cases, **BONDRONA**T can cause damage to the bones in your ear, especially with long-term use.

Tell your doctor if you get:

- chronic ear infections
- ear pain
- discharge from your ear

Low calcium levels or vitamin D deficiency

Before starting **BONDRONAT**, your doctor will check if your calcium and vitamin D levels are too low.

- You may need to take supplements if your body doesn't get enough from food.
- These should be taken as advised to avoid complications during treatment.

Injection safety

BONDRONAT must be given only into a vein (intravenously).

Incorrect administration (into an artery or under the skin) can damage surrounding tissue.

Monitoring and follow-up tests

Your doctor may do regular blood tests to check:

- how well your kidneys are working
- your calcium, phosphate, and magnesium levels

This is especially important if you have kidney problems.

Children and adolescents

BONDRONAT should not be used in children or adolescents below 18 years.

Other medicines and BONDRONAT

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

In particular, tell your healthcare provider if you are receiving a type of antibiotic injection called an 'aminoglycoside', such as gentamicin. This is because aminoglycosides and **BONDRONAT** can both lower the amount of calcium in your blood.

BONDRONAT should not be mixed with calcium-containing solutions. If you are receiving any drips or injections that contain calcium, your doctor or healthcare provider will make sure they are not mixed with **BONDRONAT**, as this can cause problems.

No interaction was observed when **BONDRONAT** was administered together with tamoxifen, or melphalan/prednisolone.

Pregnancy and breastfeeding
You should not be given **BONDRONAT** if you are pregnant or 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 healthcare provider for advice before receiving **BONDRONAT**.

Driving and using machines
Since undesirable effects such as dizziness and amnesia have been reported in patients receiving **BONDRONAT**, you should not drive, use machinery or perform any tasks that require concentration, until you are certain that **BONDRONAT**, does not adversely affect your ability to do so (see section 4).

It is not always possible to predict to what extent **BONDRONAT** 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 **BONDRONAT** affects you.

BONDRONAT contains sodium
BONDRONAT contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially “sodium-free”.

3. How to receive BONDRONAT
You will not be expected to give yourself **BONDRONAT** injection. It will be given to you by a person who is qualified to do so.

You will receive **BONDRONAT** as an intravenous infusion (a drip into a vein).

During treatment, your blood may be monitored to make sure you are receiving the correct amount of **BONDRONAT**.

Your doctor will determine how much **BONDRONAT** you will be given depending on your illness.

Your doctor may adjust your dose if you have moderate or severe kidney problems.

If you have any further questions about the use of **BONDRONAT**, please ask your doctor or pharmacist.

If more BONDRONAT is given to you than recommended
BONDRONAT will be given to you by a healthcare provider, who will ensure that the correct dose is administered. If you receive too much, your doctor will manage the overdose.

If a dose of BONDRONAT is missed
Since a health care provider will administer **BONDRONAT**, it is unlikely that the dose will be missed.
If a dose is missed, your doctor will decide when to give the next dose.

If you stop receiving BONDRONAT
Do not stop the treatment without speaking to your doctor.
If you stop receiving **BONDRONAT**, the benefits of your treatment may be reduced. For example:
- If you are receiving BONDRONAT to help prevent bone problems due to breast cancer that has spread to the bones, stopping treatment may increase the risk of bone fractures or the need for surgery or radiotherapy to the bones.
- If you are receiving BONDRONAT to lower high levels of calcium in your blood caused by a tumour, stopping treatment may allow your calcium levels to rise again, which can cause symptoms such as weakness, nausea, or confusion.

4. Possible side effects
Not all side effects reported for **BONDRONAT** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving **BONDRONAT** please consult your healthcare provider for advice.

If any of the following happens, tell your doctor immediately or go to the casualty department at your nearest hospital:
- itching, swelling of your face, lips, tongue and throat, with difficulty breathing,
- 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**. 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:

- infections
- flu-like symptoms, including fever, shaking and shivering, feeling of discomfort, fatigue, bone pain and aching muscles and joints. These symptoms usually disappear within a couple of hours or days. Talk to a nurse or doctor if any effects become troublesome or last more than a couple of days
- rise in body temperature
- low blood calcium levels (hypocalcaemia), symptoms include muscle cramps and/or tingling sensation in the fingers or lips
- headache, feeling dizzy or feeling weak
- a problem with your eyes called ‘cataracts’
- a heart rhythm problem called ‘bundle branch block’
- feeling thirsty, sore throat, changes in taste
- stomach and tummy pain, indigestion, being sick, vomiting or having diarrhoea (loose bowels)
- tooth problems.
- skin problems
- bruising
- aching joints, arthritis, or other joint problems
- pain in your bone or muscles
- swollen legs or feet
- changes in blood test results (Gamma-GT increased, creatinine increased)

Uncommon side effects

- oral thrush
- vaginitis
- a skin growth called a ‘benign skin neoplasm”
- changes in your blood cells (‘anaemia’)
- Hypophosphataemia (low level of phosphate in the blood)
- sleep problems, feeling anxious, emotional instability, or mood swings
- a condition affecting the blood vessels in your brain called ‘cerebrovascular disorder’ (stroke or brain bleeding)
- memory loss
- migraine
- pain in your nerves, damaged nerve root
- itching or tingling skin around your mouth
- increased sensitivity of sound, taste or touch or changes in smell
- stiff muscle tone (hypertonia). Symptoms may include limited range of motion, slow movements, and stiff arms and legs.
- deafness
- heart and circulatory problems (including palpitations, heart attack, hypertension (high blood pressure) and varicose veins)

- a condition caused by excessive fluid in the lungs called lung oedema. Symptoms may include difficulty in breathing, cough, chest pain and fatigue
- Stridor (a high-pitched, whistling sound most often heard while taking-in a breath)
- stomach problems such as ‘gastroenteritis” or ‘gastritis’
- mouth ulcers, swollen lips (‘cheilitis’), oral thrush
- difficulty swallowing (dysphagia)
- gall stones (cholelithiasis)
- skin rash
- hair loss
- being unable to pass water (urine), cystitis (bladder inflammation)
- kidney cyst (fluid-filled sac in the kidney)
- pelvic pain
- your body temperature getting too low (‘hypothermia’)
- a high level of alkaline phosphatase in your blood
- weight loss
- injury or pain at the injection site

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**.
For reporting of side effects directly to Adcock Ingram Limited, email: Adcock.aereports@adcock.com.

5. How to store BONDRONAT
- Store ampoules or vials at or below 25 °C. Keep in original container until required for use.
- After dilution the infusion solution is stable for 24 hours at 2 - 8 ºC (in a refrigerator).
- Store all medicines out of reach of children.
- Do not use **BONDRONAT** after the expiry date which is stated on the carton and label.
- Do not use **BONDRONAT** if you notice that the solution is not clear or contains particles.
- Infusion solutions should be used immediately after dilution. Discard any unused medicine.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information
What BONDRONAT contains
The active substance is ibandronic acid.
BONDRONAT 2 mg/2 mℓ contains 2 mg ibandronic acid per 2 mℓ, as 2,25 mg ibandronic acid, monosodium salt, monohydrate.
BONDRONAT 6 mg/6 mℓ contains 6 mg ibandronic acid per 6 mℓ, as 6,75 mg ibandronic acid,

monosodium salt, monohydrate.

The other ingredients are sodium chloride, glacial acetic acid, sodium acetate trihydrate, water for injections.

What BONDRONAT looks like and contents of the pack
BONDRONAT is a clear, colourless solution, free from visible particles.

BONDRONAT 2 mg/2 mℓ injection: is supplied as packs containing 1 or 5 ampoules/vials (2 mℓ type I glass vial with a bromobutyl rubber stopper).

BONDRONAT 6 mg/6 mℓ injection: is supplied as packs containing 1 or 5 ampoules/vials (6 mℓ type I glass vial with a bromobutyl rubber stopper).

Not all pack sizes may be marketed.

Holder of Certificate of Registration
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