BONDRONAT®

pronounced "bon-droh-nat"

contains the active ingredient ibandronic acid

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about BONDRONAT.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using BONDRONAT against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What BONDRONAT is used for

BONDRONAT contains the active ingredient ibandronic acid. It belongs to a group of medicines called bisphosphonates.

In patients with breast cancer, BONDRONAT is used to slow down the attachment, spread and growth of cancer cells within the bone, known as metastatic bone disease.

BONDRONAT works by stopping the breakdown of bone.

BONDRONAT injection can also be used to lower very high levels of calcium in the blood. High levels of calcium can occur in the presence of a tumour. This is known as hypercalcaemia of malignancy.

Your doctor may have prescribed BONDRONAT for another purpose.

Ask your doctor if you have any questions why BONDRONAT has been prescribed for you.

BONDRONAT is not addictive.

This medicine is available only with a doctor's prescription.

Before you take or are given BONDRONAT

Do not take or receive BONDRONAT if:

1. **you have low levels of calcium in your blood (called hypocalcaemia)**
2. **you have had an allergic reaction to ibandronic acid, or to any other bisphosphonate medicine or to any of the ingredients listed at the end of this leaflet**

   Some of the symptoms of an allergic reaction may include:

   - shortness of breath
   - wheezing or difficulty breathing
   - swelling of the face, lips, tongue or other parts of the body
   - rash, itching or hives on the skin.
3. **the package is torn or shows signs of tampering**
4. **the expiry date (EXP) printed on the pack has passed.**

   If you take this medicine after the expiry date has passed, it may not work as well.
5. **In addition, do not take BONDRONAT tablets if:**

   - **you have certain disorders of the food-pipe (also called oesophagus) including those that cause difficulty in swallowing**
   - **you are unable to stand or sit up straight for at least 30 minutes**

Do not give BONDRONAT to a child.

Safety and effectiveness in children have not been established.

If you are not sure if you should be receiving BONDRONAT, talk to your doctor.

Before you start to take or receive it:

Tell your doctor if:

1. **you have any other health problems, especially the following:**

- poor kidney function
- disturbances of bone and mineral metabolism
- poor dental health, such as bleeding gums
- heartburn
- swallowing or digestive problems, such as ulcers

2. **you are allergic to any other medicines, foods, dyes or preservatives**
3. **you are pregnant or intend to become pregnant**

BONDRONAT is not recommended to be used during pregnancy. Your doctor will discuss the risks and benefits of using BONDRONAT if you are pregnant.

4. **you are breast-feeding or planning to breast-feed**

   It is not known whether BONDRONAT passes into breast milk.

If you have not told your doctor about any of the above, tell them before you start receiving BONDRONAT.

Your doctor may tell you to see a dentist before receiving BONDRONAT to check for problems with your jaw or teeth.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you have bought without a prescription from a pharmacy, supermarket or healthfood shop.

Some medicines may interfere with BONDRONAT. These medicines include:

- aminoglycoside medicines, used to treat severe infections, as both agents can lower blood calcium levels
- non-steroidal anti-inflammatory drugs (also known as NSAIDs), these may cause irritation to the stomach when given with BONDRONAT tablets.
- calcium supplements, medicines used to treat low calcium levels.
- antacids, medicines used to treat indigestion and heartburn.

These medicines may be affected by BONDRONAT, or may affect how well it works. You may need to receive different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while receiving BONDRONAT.

Ask your doctor or pharmacist if you are not sure about this list of medicines.

How to take BONDRONAT tablets

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

How much to take

Take BONDRONAT tablets exactly as your doctor has prescribed.

The recommended dose of BONDRONAT is one 50 mg tablet once daily. If you have a reduced kidney function, your doctor may decide to lower your dose.

How to take it

Swallow tablets whole with a plain glass of water.

Mineral water and other drinks such as juices, coffee and tea will affect how well BONDRONAT tablets work in your body.

Do not chew or suck the tablet.

Mouth ulcers may occur if the tablet is chewed or sucked.

Do not lie down for at least 30 minutes after taking BONDRONAT tablets.

It is important to remain standing or sitting in an upright position after taking your tablet. This will help make sure the tablet reaches your stomach quickly and avoids irritating your food-pipe (oesophagus).

When to take it

BONDRONAT tablets should be taken at least 30 minutes before the first food, drink (other than plain water) or any other medicine of the day.

Food and medicines can interfere with the absorption of BONDRONAT tablets.

How long to use it

Your doctor will decide how long you should take BONDRONAT depending on your response to the medicine and the state of your disease.

If you forget to take it

If you miss a dose do not take more tablets on the same day. Return to taking one tablet per day the following day.

How BONDRONAT injection is given

How is it given

BONDRONAT injection is usually given in a hospital setting.

Your doctor will decide what dose of BONDRONAT injection you will receive, depending on your condition.

BONDRONAT injection is prepared by a healthcare professional. It is added to an infusion bag and given as a 'drip' into a vein, usually over a period of 1-2 hours.

How long to receive it

For the treatment of hypercalcaemia, only a single dose of BONDRONAT injection is normally required. However, some patients may require a second dose.

For the treatment of metastatic bone disease, BONDRONAT infusion is repeated every 4 weeks.

Your doctor will decide how long you should receive BONDRONAT depending on your response to the medicine and the state of your disease.

If you take or receive too much (overdose)

Immediately telephone your doctor, or Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital if you think you or anyone else may have taken or been given too much BONDRONAT. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep telephone numbers for these places handy.

If you are not sure what to do, contact your doctor or pharmacist.

While you are taking BONDRONAT

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are receiving BONDRONAT.

Tell your doctor immediately if you experience allergic reactions such as chest tightness, wheezing, severe dizziness or lightheadedness, swelling of the lips or skin rash during or after receiving BONDRONAT.

Tell your doctor if you become pregnant while receiving BONDRONAT.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor that you are receiving BONDRONAT if you are going to have any laboratory tests.

Be sure to brush and floss your teeth daily, and have regular dental check-ups with your dentist.

If you develop pain in your mouth, teeth or jaw, or have bleeding gums, or have an unusual feeling in your teeth or gums, tell your doctor and dentist immediately.

BONDRONAT may cause jaw-bone problems in some people. Jaw-bone problems may include infection, and delayed healing after teeth are pulled out or other dental work that involves drilling into the jaw.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

Things you must not do

Do not stop taking BONDRONAT or change the dose without first checking with your doctor.

Do not let yourself run out of medicine over the weekend or on holidays.

Do not give BONDRONAT to anyone else even if they have the same condition as you.

Do not use BONDRONAT to treat other complaints unless your doctor tells you to.

Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting a pharmacist.

Things to be careful of

Be careful driving or operating machinery until you know how BONDRONAT affects you.

The effect of BONDRONAT on the ability to drive or use machinery has not been studied. However BONDRONAT is not expected to affect your ability to drive a car or operate machinery.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well after you have been given BONDRONAT.

BONDRONAT helps most people with high blood calcium levels or people with metastatic bone disease and breast cancer, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or nurse if you notice any of the following and they worry you:

- a rise in body temperature or feeling hot
- fever, chills, headache, sweating, bone or muscle pain, similar to the flu
- muscle aches
- diarrhoea
- indigestion
- vomiting, abdominal pain
- dizziness
- headache
- nausea

These are the more common side effects of BONDRONAT. Mostly these are mild and last only hours up to a couple of days.

Tell your doctor and dentist immediately if you notice any of the following:

- tooth, gum or jaw pain
- bleeding gums
- sudden loosening of teeth
- infection in the mouth, poor healing of gums
- numbness/heaviness in the jaw
- difficulty swallowing or pain when swallowing
- irritation in the food-pipe (also called oesophagus)
- new or worsening heartburn
- sore mouth, mouth ulcers or cold sores

- irritated eyes, blurred vision, eye pain, sensitivity to light, runny or itchy eyes
- 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

Some of these side effects are rare but they may be serious.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- difficulty breathing, chest tightness or wheezing
- severe lightheadedness
- severe skin rash, itching, hives
- swelling of the face, lips, mouth
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After taking BONDRONAT tablets

Storage

Keep your tablets in the blister pack until it is time to take them.

If you take the tablets out of the packaging they will not keep well.

Keep the blister pack in a cool dry place where the temperature stays below 30°C.

Do not store BONDRONAT tablets, or any other medicine, in a bathroom or near a sink.

Do not leave it in the car or on window sills or other places where it may get hot, even for a short period.

Heat and dampness can destroy some medicines.

Keep BONDRONAT tablets where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking BONDRONAT tablets, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

Product description

Availability

BONDRONAT injection (6 mg/6 mL) is available in packs of one vial.

BONDRONAT tablets are available in blister packs of 28.

What BONDRONAT looks like

BONDRONAT injection is a clear to colourless solution, which is mixed with a sterile infusion solution before being administered as "a drip".

BONDRONAT 50 mg tablets are white to off-white oblong tablet, with "L2" engraved on one side and "IT" engraved on the other side.

Ingredients

BONDRONAT injection solution

Active ingredient

- ibandronic acid

Inactive ingredients

- sodium chloride
- glacial acetic acid
- sodium acetate
- water for injections

BONDRONAT tablet

Active ingredient

- ibandronic acid

Inactive ingredients

- lactose monohydrate
- microcrystalline cellulose
- povidone
- crospovidone
- stearic acid
- colloidal anhydrous silica
- hypromellose
- titanium dioxide
- purified talc
- macrogol 6000

BONDRONAT injection and tablets do not contain sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

Atnahs Pharma Australia Pty Ltd

Level 10 / 10 Shelley Street,

Sydney, NSW, 2000, Australia

BONDRONAT is distributed by:

Clinect Pty Ltd

120 - 132 Atlantic Drive

Keysborough, VIC 3173, Australia

Customer enquiries: 1800 899 005

Please check with your pharmacist for the latest Consumer Medicine Information.

Australian Registration Numbers

- 6 mg/6 mL injection: AUST R 98008
- 50 mg tablets: AUST R 119673

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