

# BONDRONAT®

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### 1. Why am I using BONDRONAT?

BONDRONAT contains the active ingredient ibandronic acid. 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 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.

For more information, see Section [1. Why am I using BONDRONAT?](#) in the full CMI.

### 2. What should I know before I take or receive BONDRONAT?

Do not use if you have ever had an allergic reaction to BONDRONAT or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use BONDRONAT?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with BONDRONAT and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### **4. How do I use BONDRONAT?**

- The recommended dose of BONDRONAT tablets is one 50 mg tablet once daily.
- Your doctor will decide what dose of BONDRONAT injection you will receive, depending on your condition. BONDRONAT is added to an infusion bag and given as a 'drip' into a vein, usually over a period of 1-2 hours.

More instructions can be found in Section [4. How do I use BONDRONAT?](#) in the full CMI.

## 5. What should I know while using BONDRONAT?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>● Remind any doctor, dentist, nurse or pharmacist you visit that you are using BONDRONAT.</li><li>● Be sure to brush and floss your teeth daily, and have regular dental check-ups with your dentist.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>● Do not stop taking BONDRONAT or change the dose without first checking with your doctor.</li><li>● Do not let yourself run out of medicine over the weekend or on holidays.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>● Be careful before you drive or operate any machines or tools until you know how BONDRONAT affects you.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>● Keep the blister pack in a cool dry place where</li></ul>

	the temperature stays below 30°C.
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For more information, see Section [5. What should I know while using BONDRONAT?](#) in the full CMI.

## **6. Are there any side effects?**

All medicines can have side effects. Sometimes they are serious, most of the time they are not. The most common side effects are 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, and nausea.

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

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# **BONDRONAT®** (pronounced "bon-droh-nat")

**Active ingredient(s):** *ibandronic acid*

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## **Consumer Medicine Information (CMI)**

This leaflet provides important information about using BONDRONAT. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using BONDRONAT.**

**Where to find information in this leaflet:**

- [1. Why am I using BONDRONAT?](#)
- [2. What should I know before I use BONDRONAT?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use BONDRONAT?](#)
- [5. What should I know while using BONDRONAT?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## **1. Why am I using BONDRONAT?**

**BONDRONAT contains the active ingredient ibandronic acid.** BONDRONAT 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.

## **2. What should I know before I take or receive BONDRONAT?**

### **Warnings**

#### **Do not use BONDRONAT if:**

- you are allergic to ibandronic acid, or to any other biphosphonate medicine or 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

Always check the ingredients to make sure you can use this medicine.

- you have low levels of calcium in your blood (called hypocalcaemia)
- you have certain disorders of the food-pipe (also called oesophagus) including those that cause difficulty swallowing
- you are unable to stand or sit up straight for at least 30 minutes
- the package is torn or shows signs of tampering
- 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.

**Do not give BONDRODAT to a child.** Safety and effectiveness in children have not been established.

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

**Check with your doctor if you:**

- have any other medical conditions, 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
- take any medicines for any other condition
- are allergic to any other medicines, foods, dyes or preservatives

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

Check with your doctor if 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.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not known whether BONDRONAT passes into breast milk.

### **3. What if I am taking other medicines?**

Tell your doctor, nurse or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

#### **Some medicines may interfere with BONDROSTAT and affect how it works.**

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 BONDROSTAT tablets
- calcium supplements, medicines used to treat low calcium levels
- antacids, medicines used to treat indigestion and heartburn

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These medicines may be affected by BONDROSTAT, 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.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect BONDROSTAT.**

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

## **4. How do I use BONDRONAT?**

### **How much to take - BONDRONAT tablets**

- 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.
- Follow the instructions provided and use BONDRONAT until your doctor tells you to stop.

### **When to take BONDRONAT tablets**

- **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.
- 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 are at low risk of broken bones, your doctor may put you on a break from BONDRONAT after 3 to 5 years.

## How to take BONDRONAT tablets

- **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 on 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).

## If you forget to take BONDRONAT tablets

BONDRONAT should be used regularly at the same time each day. If you miss your dose at the usual time, do not take more tablets on the same day. Return to taking one tablet per day the following day.

## How BONDRONAT injection is 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 BONDRONAT injection**

- 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 BONDRONAT**

If you think that you have used too much BONDRONAT, you may need urgent medical attention.

### **You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using BONDRONAT?

### Things you should do

- Tell all doctors, dentists, nurses 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.
- If you develop any thigh, hip or groin pain, tell your doctor immediately.
- Be sure to keep all of your appointments with your doctor so that your progress can be checked.

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.

## **Things you should 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.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools 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 affective your ability to drive a car or operate machinery.

## **Looking after your medicine**

- 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.**

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

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

**Keep it where young children cannot reach it.**

## **Getting rid of any unwanted medicine**

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

Do not use this medicine after the expiry date.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

## Less serious side effects

Less serious side effects	What to do
<p><b>Digestive system-related:</b></p> <ul style="list-style-type: none"><li>• diarrhoea</li><li>• indigestion</li><li>• vomiting, abdominal pain</li><li>• nausea</li></ul> <p><b>General body:</b></p> <ul style="list-style-type: none"><li>• a rise in body temperature or feeling hot</li><li>• fever, chills, headache, sweating, bone or muscle pain, similar to the flu</li><li>• muscle aches</li></ul> <p><b>Head-related:</b></p> <ul style="list-style-type: none"><li>• dizziness</li><li>• headache</li></ul>	<p><b>Speak to your doctor or nurse if you have any of these less serious side effects and they worry you.</b></p>

## Serious side effects

Serious side effects	What to do
<p><b>Mouth-related:</b></p> <ul style="list-style-type: none"><li>• tooth, gum or jaw pain</li><li>• bleeding gums</li><li>• sudden loosening of teeth</li><li>• infection in the mouth, poor healing of gums</li><li>• numbness/heaviness in the jaw</li><li>• difficulty swallowing or pain when swallowing</li><li>• sore mouth, mouth ulcers or cold sores</li></ul> <p><b>Digestive system-related:</b></p> <ul style="list-style-type: none"><li>• irritation in the food-pipe (also called oesophagus)</li><li>• new or worsening heartburn</li></ul> <p><b>Eye-related:</b></p> <ul style="list-style-type: none"><li>• irritated eyes, blurred vision, eye pain,</li></ul>	<p><b>Tell your doctor, nurse or dentist immediately if you notice any of these serious side effects.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p>sensitivity to light, runny or itchy eyes</p> <p><b>Bone-related:</b></p> <ul style="list-style-type: none"> <li>● 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.</li> </ul> <p><b>Other:</b></p> <ul style="list-style-type: none"> <li>● severe blisters and bleeding in the lips, eyes, mouth, nose and genitals</li> </ul>	
<p><b>Allergic reaction:</b></p> <ul style="list-style-type: none"> <li>● difficulty breathing, chest tightness or wheezing</li> <li>● severe lightheadedness</li> <li>● severe skin rash, itching, hives</li> <li>● swelling of the face, lips, mouth</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

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

### What BONDRONAT injection solution contains

<b>Active ingredient (main ingredient)</b>	ibandronic acid
<b>Other ingredients (inactive ingredients)</b>	sodium chloride glacial acetic acid water for injections

<b>Potential allergens</b>	N/A
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## What BONDRODAT tablets contain

<b>Active ingredient (main ingredient)</b>	ibandronic acid
<b>Other ingredients (inactive ingredients)</b>	lactose monohydrate microcrystalline cellulose povidone crospovidone stearic acid colloidal anhydrous silica hypromellose titanium dioxide purified talc macrogol 6000
<b>Potential allergens</b>	lactose

**Do not take this medicine if you are allergic to any of these ingredients.**

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

## **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" (AUST R 98008).

BONDRONAT 50 mg tablets are white to off-white oblong tablet, with "L2" engraved on one side and "IT" engraved on the other side (AUST R 119673).

## **Who distributes BONDRONAT**

### **Sponsor:**

Atnahs Pharma Australia Pty Ltd

Level 10 / 10 Shelley Street

Sydney, NSW, 2000

Australia

### **Distributor:**

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.

This leaflet was prepared in February 2023.