

## ALVODRONIC 150mg

film-coated tablets

IBANDRONIC ACID

---

*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

---

*• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •*

---

### What is in this leaflet?

1. What Ibandronic acid is and what it is used for
2. Before you take Ibandronic acid
3. How to take Ibandronic acid
4. Possible side effects
5. How to store Ibandronic acid

#### 1. WHAT IBANDRONIC ACID IS AND WHAT IT IS USED FOR

Ibandronic acid belongs to a group of medicines called bisphosphonates. It does not contain hormones. Ibandronic acid may reverse bone loss by stopping more loss of bone and increasing bone mass in most women who take it, even though they won't be able to see or feel a difference. Ibandronic acid may help lower the chances of breaking bones (fractures). This reduction in fractures was shown for the spine but not for the hip. Ibandronic acid is prescribed to you to treat postmenopausal osteoporosis because you have an increased risk of fractures. Osteoporosis is a thinning and weakening of the bones, which is common in women after the menopause. At the menopause, a woman's ovaries stop producing the female hormone, oestrogen, which helps to keep her skeleton healthy.

The earlier a woman reaches the menopause, the greater her risk of fractures in osteoporosis. Other things that can increase the risk of fractures include:

- not enough calcium and vitamin D in the diet
- smoking, or drinking too much alcohol
- not enough walking or other weight-bearing exercise
- a family history of osteoporosis

Many people with osteoporosis have no symptoms. If you have no symptoms you may not know if you have the condition. However, osteoporosis makes you more likely to break bones if you fall or hurt yourself. A broken

bone after the age of 50 may be a sign of osteoporosis. Osteoporosis can also cause back pain, height loss and a curved back.

Ibandronic acid prevents loss of bone from osteoporosis, and helps to rebuild bone. Therefore Ibandronic acid makes bone less likely to break.

A healthy lifestyle will also help you to get the most benefit from your treatment. This includes eating a balanced diet rich in calcium and vitamin D; walking or any other weight-bearing exercise; not smoking; and not drinking too much alcohol.

## **2. BEFORE YOU TAKE IBANDRONIC ACID**

### **Do not take Ibandronic acid**

- If you are allergic (hypersensitive) to ibandronic acid, or to any of the other ingredients of Alvodronic tablets.
  - 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.

### **Children and teenagers**

Do not give Ibandronic acid to children or teenagers.

### **Take special care with Ibandronic acid**

Some people need to be especially careful while they're taking Ibandronic acid. Check with your doctor:

- If you have any disturbances of mineral metabolism (such as vitamin D deficiency).
- If your kidneys are not functioning normally.
- If you have any swallowing or digestive problems.
- If you are under dental treatment or will undergo dental surgery, tell your dentist that you are being treated with Ibandronic acid.

Irritation, inflammation or ulceration of the oesophagus (the tube connecting your mouth with your stomach) often with symptoms of severe pain in the chest, severe pain after swallowing food and/or drink, severe nausea, or vomiting may occur, especially if you do not drink a full glass of plain water and/or if you lie down within an hour of taking Ibandronic acid. If you develop these symptoms, stop taking Ibandronic acid and tell your doctor straight away.

### **Taking other medicines**

Please tell your doctor or pharmacist if you are taking, or have recently taken any other medicines, including medicines obtained without prescription. Especially:

- Supplements containing calcium, magnesium, iron or aluminium, as they could possibly influence the effects of Ibandronic acid.
- Aspirin and other non-steroidal anti-inflammatory medicines (NSAIDs) (including ibuprofen, diclofenac sodium and naproxen) may irritate the stomach and intestine. Bisphosphonates (like Ibandronic acid) may also do so.

So be especially careful if you take painkillers or anti-inflammatory while you're taking Ibandronic acid.

After swallowing your monthly Alvodronic tablet, wait for 1 hour before taking any other medication, including indigestion tablets, calcium supplements, or vitamins.

### **Taking Ibandronic acid with food and drink:**

Do not take Ibandronic acid with food.

Ibandronic acid is less effective if it's taken with food. You can drink plain water but no other drinks. (See section 3. HOW TO TAKE IBANDRONIC ACID).

### ***Pregnancy and breast feeding***

Do not take Ibandronic acid if you're pregnant or breast feeding. If you're breast feeding, you may need to stop in order to take Ibandronic acid.

Ask your doctor or pharmacist for advice before taking any medicines.

### ***Driving and using machines***

You can drive and use machines as it's very unlikely that Ibandronic acid will affect your ability to drive and use machines.

### ***Important information about some of the ingredients of Ibandronic acid***

Ibandronic acid contains an ingredient called lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

## **3. HOW TO TAKE IBANDRONIC ACID**

Always take Ibandronic acid exactly as your doctor has told you. If you're not sure about anything, ask your doctor or pharmacist.

### ***Dose***

The usual dose of Ibandronic acid is one tablet once a month.

### ***Method and route of administration***

#### **Taking your monthly tablet**

It's important to follow these instructions carefully.

They are designed to help your Alvodronic tablet reach your stomach quickly, so it's less likely to cause irritation.

#### **Frequency of administration**

- Take one Alvodronic 150 mg tablet once a month.
  - Choose one day of the month that will be easy to remember. You can choose either the same date (such as the 1st of each month) or the same day (such as the first Sunday of each month) to take your Alvodronic tablet. Choose the date that best fits your routine.
  - Take your Alvodronic tablet at least 6 hours after you last had anything to eat or drink except plain water.
  - Take your Alvodronic tablet
    - after you first get up for the day, and
    - before you have anything to eat or drink (on an empty stomach)
  - Swallow your tablet with a full glass of plain water (at least 180 ml). Do not take your tablet with mineral water, fruit juice or any other drinks.
  - Swallow your tablet whole - do not chew it, crush it or let it dissolve in your mouth.
  - For the next hour (60 minutes) after you've taken your tablet
    - do not lie down; if you do not stay upright (standing or sitting), some of the medicine could leak back into your oesophagus
    - do not eat anything
    - do not drink anything (except plain water if you need it)
    - do not take any other medicines.
  - After you've waited for an hour, you can have your first food and drink of the day. Once you've eaten, it's OK to lie down if you wish, and to take any other medicine you need.
- Do not take your tablet at bedtime or before you get up for the day.

## Duration of the treatment

### ***Continuing to take Ibandronic acid***

It's important to keep taking Ibandronic acid every month, as long as your doctor prescribes it for you. Ibandronic acid can treat osteoporosis only as long as you keep taking it.

### ***If you take too much Ibandronic acid***

If you've taken more than one tablet by mistake, drink a full glass of milk and talk to your doctor straight away. Do not make yourself vomit, and do not lie down - this could cause Ibandronic acid to irritate your oesophagus.

### ***If you forget a dose***

**If you forget to take your tablet on the morning** of your chosen day, **do not take** a tablet later in the day. Instead, consult your calendar and find out when your next scheduled dose is:

**If your next scheduled dose is only 1 to 7 days away...** You should wait until the next scheduled dose is due and take it as normal; then, continue taking one tablet once a month on the scheduled days you've marked on your calendar.

**If your next scheduled dose is more than 7 days away...** You should take one tablet the next morning after the day you remember; then, continue taking one tablet once a month on the scheduled days you've marked on your calendar.

**Never take two Ibandronic tablets within the same week.**

## 4. POSSIBLE SIDE EFFECTS

Like all medicines, Ibandronic acid can cause side effects, although not everybody gets them.

Talk to a nurse or a doctor straight away if you notice any of the following serious side effects - you may need urgent medical treatment:

- rash, itching, swelling of your face, lips, tongue and throat, with difficulty breathing. You may be having an allergic reaction to the medicine.
- severe pain in the chest, severe pain after swallowing food or drink, severe nausea, or vomiting.
- flu-like symptoms (if any effects become troublesome or last more than a couple of days).
- pain or sore in your mouth or jaw
- eye pain and inflammation (if prolonged).

### ***Other possible side effects***

**Common** (affects less than 1 in 10 people)

- headache
- heartburn, stomach pain (such as "gastroenteritis" or "gastritis"), indigestion, nausea, having diarrhoea or constipation
- rash
- pain or stiffness in your muscles, joints, or back
- flu-like symptoms (including fever, shaking and shivering, feeling of discomfort, fatigue, bone pain and aching muscles and joints)
- fatigue.

**Uncommon** (affects less than 1 in 100 people)

- bone pain
- feeling weak
- dizziness
- flatulence.

**Rare** (affects less than 1 in 1000 people):

- hypersensitivity reaction; swelling of the face, lips and mouth (see allergy)
- itching
- eye pain or inflammation

- unusual fracture of the thigh bone particularly in patients on long-term treatment for osteoporosis may occur rarely. Contact your doctor if you experience pain, weakness or discomfort in your thigh, hip or groin as this may be an early indication of a possible fracture of the thigh bone.

**Very rare** (affects less than 1 in 10000 people)

- a condition involving exposed bone in the mouth called “osteonecrosis of the jaw”.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### *5. HOW TO STORE IBANDRONIC ACID*

Keep out of the reach and sight of children. This medicinal product does not require any special storage conditions.

Do not use after the expiry date which is stated on the blister and carton after “EXP”. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

This leaflet was last approved in 06/2012.