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Package leaflet: Information for the user
Ibandronic acid Pinewood
150 mg film-coated tablets
ibandronic acid

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. See section 4.

What is in this leaflet

1. What Ibandronic acid Pinewood is and what it is used for
2. What you need to know before you take Ibandronic acid Pinewood
3. How to take Ibandronic acid Pinewood
4. Possible side effects
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1. What Ibandronic acid Pinewood is and what it is used for
Ibandronic acid Pinewood belongs to a group of medicines called bisphosphonates. It contains the active substance ibandronic acid. Ibandronic acid Pinewood may reverse bone loss by stopping more loss of bone and increasing bone mass in most women who take it, even though they will not be able to see or feel a difference. Ibandronic acid Pinewood 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 Pinewood 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

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. What you need to know before you take Ibandronic acid Pinewood
Do not take Ibandronic acid Pinewood

- If you are allergic to ibandronic acid, or any of the other ingredients of this medicine (listed in section 6).
- If you have certain problems with your gullet/food pipe (oesophagus) such as narrowing or difficulty swallowing.
- If you cannot 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.

Warnings and precautions
Talk to your doctor or pharmacist before taking Ibandronic acid Pinewood.

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 ibandronic acid for osteoporosis. ONJ can also occur after stopping treatment.

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.

Before receiving treatment, tell your doctor/nurse (healthcare professional) if:

- you have any problems with your mouth or teeth such as poor dental health, gum disease, 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 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 Ibandronic acid Pinewood.

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 Ibandronic acid Pinewood.

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

Some people need to be especially careful while they are taking Ibandronic acid Pinewood. Talk to your doctor before taking Ibandronic acid Pinewood:

- 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.

Irritation, inflammation or ulceration of the gullet/food pipe (oesophagus) 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 water and/or if you lie down within an hour of taking **Ibandronic acid Pinewood**. If you develop these symptoms, stop taking Ibandronic acid Pinewood and tell your doctor straight away (see section 3).

Children and adolescents
Do not give Ibandronic acid Pinewood to children or adolescents below 18 years.

Other medicines and Ibandronic acid Pinewood
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Especially:

- **Supplements containing calcium, magnesium, iron or aluminium**, as they could possibly influence the effects of Ibandronic acid Pinewood.
- Acetylsalicylic acid and other non-steroidal anti-inflammatory medicines (NSAIDs) (including ibuprofen, diclofenac sodium and naproxen) may irritate the stomach and intestine. Ibandronic acid Pinewood may also do so. So be especially careful if you take painkillers or anti-inflammatories while you are taking Ibandronic acid Pinewood.

After swallowing your monthly Ibandronic acid Pinewood tablet, **wait for 1 hour before taking any other medicine**, including indigestion tablets, calcium supplements or vitamins.

Ibandronic acid Pinewood with food and drink
Do not take Ibandronic acid Pinewood with food. Ibandronic acid Pinewood is less effective if it is taken with food. **You can drink water but no other drinks.**

After you have taken Ibandronic acid Pinewood, please wait for 1 hour before you can have your first food and further drinks. (see section 3 "How to take Ibandronic acid Pinewood").

Pregnancy and breast-feeding
Ibandronic acid Pinewood is for use only by postmenopausal women and must not be taken by women who could still have a baby. Do not take Ibandronic acid Pinewood if you are pregnant or breast-feeding. Ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
You can drive and use machines as it is expected that Ibandronic acid Pinewood has no or negligible effect on your ability to drive and use machines.

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

Ibandronic acid Pinewood contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

3. How to take Ibandronic acid Pinewood
Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

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

Taking your monthly tablet
It is important to follow these instructions carefully. They are designed to help your Ibandronic acid Pinewood tablet reach your stomach quickly, so it is less likely to cause irritation.

- **Take one Ibandronic acid Pinewood 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 Ibandronic acid Pinewood tablet. Choose the date that best fits your routine.
- Take your Ibandronic acid Pinewood tablet **at least 6 hours after you last had anything** to eat or drink except water.
- Take your Ibandronic acid Pinewood tablet
 - **after you first get up for the day, and**
 - **before you have anything to eat or drink** (on an empty stomach)

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• **Swallow your tablet with a full glass of water** (at least 180 mL).

Do not take your tablet with water with a high concentration of calcium, fruit juice or any other drinks. If there is a concern regarding potentially high levels of calcium in the tap water (hard water), it is advised to use bottled water with a low mineral content.

• **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 have 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 water if you need it)

• **do not take any other medicines**

• After you have 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 medication you need.

Continuing to take Ibandronic acid Pinewood

It's important to keep taking Ibandronic acid Pinewood every month, as long as your doctor prescribes it for you. After 5 years of using Ibandronic acid Pinewood, please consult with your doctor whether you should continue to take Ibandronic acid Pinewood.

If you take more Ibandronic acid Pinewood than you should

If you have 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 Pinewood to irritate your oesophagus.

If you forget to take Ibandronic acid Pinewood

• If you forget to take your tablet in 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 you forgot to take your tablet on your chosen day and your next scheduled dose is only 1 to 7 days away...**

Never take two Ibandronic acid Pinewood tablets within the same week. 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 have marked on your calendar.

• **If you forgot to take your tablet on your chosen day and 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 have marked on your calendar.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine 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:

Uncommon (may affect up to 1 in 100 people)

• severe pain in the chest, severe pain after swallowing food or drink, severe nausea, or vomiting, difficulty in swallowing. You may have a severe inflammation of your gullet/food pipe, possibly with sores or constriction of the gullet/food pipe.

Rare (may affect up to 1 in 1,000 people)

• itching, swelling of your face, lips, tongue and throat, with difficulty breathing
• 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.

Very rare (may affect up to 1 in 10,000 people)

• pain or sore in your mouth or jaw. You may have early signs of severe jaw problems (necrosis (dead bone tissue) in the jaw bone)
• talk to your doctor if you have ear pain, discharge from the ear, and/or an ear infection. These could be signs of bone damage in the ear
• serious, potentially life-threatening allergic reaction
• severe adverse skin reactions.

Other possible side effects

Common (may affect up to 1 in 10 people)

• headache
• heartburn, discomfort in swallowing, stomach or tummy pain (may be due to an inflammation of the stomach), indigestion, nausea, having diarrhoea (loose bowels)
• muscle cramps, stiffness of your joints and limbs
• flu-like symptoms, including fever, shaking and shivering, feeling of discomfort, bone pain and aching muscles and joints. Talk to a nurse or doctor if any effects become troublesome or last more than a couple of days
• rash

Uncommon (may affect up to 1 in 100 people)

• dizziness
• flatulence (farting, feeling bloated)
• back pain
• feeling tired and exhausted
• asthma attacks

Rare (may affect up to 1 in 1,000 people)

• inflammation of the duodenum (first section of the bowel) causing stomach pain
• hives

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system to: HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie e-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ibandronic acid Pinewood

Keep this medicine out of the sight and reach of children.

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

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Ibandronic acid Pinewood contains

• The active substance is ibandronic acid. Each film-coated tablet contains 150 mg ibandronic acid (as sodium monohydrate).

• The other ingredients are:

tablet core: Povidone, cellulose microcrystalline, maize starch pregelatinised, crospovidone, silica colloidal anhydrous, glycerol dibehenate.

tablet coat: Opadry OY-LS-28908 (White II) consisting of: hypromellose, lactose monohydrate, titanium dioxide (E171), macrogol 4000.

What Ibandronic acid Pinewood looks like and contents of the pack

Ibandronic acid Pinewood 150 mg film-coated tablets are white, round, biconvex tablets.

Ibandronic acid Pinewood 150 mg film-coated tablets are supplied in a cardboard box containing the appropriate number of PA/Aluminium/PVC- Aluminium foil blisters (alu-alu blister) containing 1 or 3 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Pinewood Laboratories Limited, Ballymacarbray, Clonmel, Co. Tipperary, Ireland.

Manufacturer

Pharmathen S.A, 6 Dervenakion Str., 153 51 Pallini, Attiki, Greece
Pharmathen International SA, Sapes Industrial Park, Block 5, 69300 Rodopi, Greece

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium	Ibandronate Mithra
Bulgaria	Quodixor
Ireland	Ibandronic acid Pinewood 150 mg film-coated tablets
Luxemburg	Ibandronate Mithra
Poland	Quodixor
Portugal	Quodixor
Romania	Quodixor 150 mg comprimate filmate
United Kingdom	Quodixor

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PINEWOOD
HEALTHCARE
Ballymacarbray, Co. Tipperary.

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