Package leaflet: Information for the patient
Ibandronic acid 50 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 50 mg is and what it is used for
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1. WHAT IBANDRONIC ACID 50 MG IS AND WHAT IT IS USED FOR

Ibandronic acid 50 mg contains the active substance ibandronic acid. This belongs to a group of medicines called bisphosphonates.

Ibandronic acid 50 mg is used in adults and prescribed to you if you have breast cancer that has spread to your bones (called bone "metastases").

- It helps to prevent your bones from breaking (fractures).
- It also helps to prevent other bone problems that may need surgery or radiotherapy.

Ibandronic acid 50 mg works by reducing the amount of calcium that is lost from your bones. This helps to stop your bones from getting weaker.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE IBANDRONIC ACID 50 MG

Do not take Ibandronic acid 50 mg:
- if you are allergic to ibandronic acid or any of the other ingredients of this medicine (listed in section 6).
- if you have problems with your food pipe/gullet (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 ever had low calcium in your blood.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Ibandronic acid 50 mg.

Warnings and precautions

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 50 mg for cancer-related conditions. 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 (health care professional) if:
- you have any problems with your mouth or teeth such as poor dental health, gum disease, or a planned tooth extraction
- you don't 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 50 mg.

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 50 mg.

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

Atypical fractures of the long bones, such as in the forearm bone (ulna) and the shinbone (tibia), have also been reported in patients receiving long-term treatment with ibandronic acid. These fractures occur after minimal, or no trauma and some patients experience pain in the area of the fracture prior to presenting with a completed fracture.

Talk to your doctor or pharmacist before taking Ibandronic acid 50 mg:
- if you are allergic to any other bisphosphonates
- if you have any swallowing or digestion problems.
- if you have high or low blood levels of vitamin D or any other minerals
- if you have kidney 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 takingIibandronic acid 50 mg. If you develop these symptoms, stop taking Ibandronic acid 50 mg and tell your doctor straight away (see sections 3 and 4).

Children and adolescents
Ibandronic acid 50 mg should not be used in children and adolescents below the age of 18 years.

Other medicines and Ibandronic acid 50 mg

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Ibandronic acid 50 mg can affect the way some other medicines work. Also some other medicines can affect the way Ibandronic acid 50 mg works.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- supplements containing calcium, magnesium, iron or aluminium
- acetylsalicylic acid and non-steroidal anti-inflammatory medicines called "NSAIDs", such as ibuprofen or naproxen. This is because NSAIDs, and Ibandronic acid 50 mg can both irritate your stomach and gut
- a type of antibiotic injection called "aminoglycoside" such as gentamicin. This is because aminoglycosides and Ibandronic acid 50 mg can both lower the amount of calcium in your blood.

Taking medicines that reduce stomach acid such as cimetidine and ranitidine, may slightly increase the effects of Ibandronic acid 50 mg.

Ibandronic acid 50 mg with food and drink
Do not take Ibandronic acid 50 mg with food or any other drinks except water as Ibandronic acid 50 mg is less effective if it is taken with food or drink (see section 3).

Take Ibandronic acid 50 mg at least 6 hours after you last had anything to eat, drink or any other medicines or supplements (e.g. products containing calcium (milk), aluminum, magnesium and iron) except water. After taking your tablet wait at least 30 minutes. Then you can have your first food and drink, and take any medicines or supplements (see section 3).

Pregnancy and breast feeding
Do not take Ibandronic acid 50 mg if you are pregnant, planning to get pregnant or if you are 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's expected that ibandronic acid has no or negligible effect on your ability to drive and use machines. Talk to your doctor first if you want to drive, use machine or tools.

Ibandronic acid 50 mg contains lactose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
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This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. HOW TO TAKE IBANDRONIC ACID 50 MG

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
Take your tablet at least 6 hours after you last had anything to eat, drink or any other medicines or supplements except water. Water with a high concentration of calcium should not be used. If there is 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.

Your doctor may do regular blood tests while you are taking Ibandronic acid 50 mg. This is to check that you are being given the right amount of medicine.

Taking this medicine
It is important that you take Ibandronic acid 50 mg at the right time and in the right way. This is because it can cause irritation, inflammation or ulcers in your food pipe/gullet (oesophagus).

You can help stop this happening by doing the following:

- Take your tablet as soon as you get up for the day before having your first food, drink, any medicine or supplements.
- Take your tablet with a full glass of water only (about 200 mL). Do not take your tablet with any drink other than water
- Swallow the tablet whole. Do not chew, suck or crush the tablet. Do not let the tablet dissolve in your mouth.
- After taking your tablet, wait at least 30 minutes. Then you can have your first food and drink, and take any medicines or supplements.
- Stay upright (sitting or standing) while taking your tablet and for the next hour (60 minutes). Otherwise, some of the medicine could leak back into your food pipe/gullet (oesophagus).

How much to take
The usual dose of Ibandronic acid 50 mg is one tablet each day. If you have moderate kidney problems, your doctor may reduce your dose to one tablet every other day. If you have severe kidney problems, your doctor may reduce your dose to one tablet each week.

If you take more Ibandronic acid 50 mg than you should
If you take too many tablets talk to a doctor or go to hospital straight away. Drink a full glass of milk before you go. Do not make yourself sick. Do not lie down.

If you forget to take Ibandronic acid 50 mg
Do not take a double dose to make up for a forgotten dose. If you are taking a tablet each day, skip the missed dose completely. Then carry on as usual the next day. If you are taking a tablet every other day or once a week, ask your doctor or pharmacist for advice.

If you stop taking Ibandronic acid 50 mg
Keep taking Ibandronic acid 50 mg for as long as your doctor tells you. This is because the medicine will only work if it is taken all the time.

Continuing to receive Ibandronic acid 50 mg
It's important to keep receiving Ibandronic acid 50 mg every month, as long as your doctor prescribes it for you. After 3-5 years of receiving Ibandronic acid 50 mg , please consult with your doctor whether you should continue to receive Ibandronic acid 50 mg.

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:

Common (may affect up to 1 in 10 people):

- feeling sick, heartburn and discomfort in swallowing (inflammation of your gullet/ food pipe)

Uncommon (may affect less than 1 in 100 people):
- severe stomach pain. This could be a sign of an ulcer of the first section of the bowel (duodenum) that is bleeding, or that your stomach is inflamed (gastritis)

Rare (may affect up to 1 in 1,000 people):
- 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.
- itching, swelling of your face, lips, tongue and throat, with difficulty breathing. You may be having a serious, potentially life threatening allergic reaction.
- severe adverse skin reactions

Not known (frequency cannot be estimated from the available data):
- asthma attack

Other possible side effects

Common (may affect up to **1 in 10 people)**:
- tummy pain, indigestion
- low calcium levels in your blood
- weakness

Uncommon (may affect **less than 1 in 100 people)**:
- chest pain
- itching or tingling skin (paraesthesia)
- flu-like symptoms, feeling generally unwell or in pain
- dry mouth, strange taste in your mouth or difficulty swallowing
- anaemia (bloodlessness)
- high levels of urea or high levels of parathyroid hormone in your blood.

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 Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE IBANDRONIC ACID 50 MG

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 blister and carton 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 50 mg contains

- The active substance is 56.25 mg of ibandronic acid, monosodium salt, monohydrate, equivalent to 50 mg of ibandronic acid.

- The other ingredients are lactose monohydrate, crospovidone (E1202), microcrystalline cellulose (E460), colloidal anhydrous silica (E551), sodium stearyl fumarate (tablet core); polyvinyl alcohol, macrogol/PEG 3350, talc (E553b) and titanium dioxide (E171) (tablet coating).

What Ibandronic acid 50 mg looks like and contents of the pack

Ibandronic acid tablets are white to off-white, oblong tablets inscripted with “I9BE” on one side and “50” on the other side.
They are available in blister packs of 1, 7, 10, 14, 20, 21, 28, 30, 42, 50, 56, 60, 84, 90, 100, 126, 168 and 210 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Consilient Health Ltd., Floor 3, Block 3, Miesian Plaza, Dublin 2, D02 Y754, Ireland.

Manufacturers:
Synthon BV, Microweg 22, 6545 CM, Nijmegen, The Netherlands

Synthon Hispania S.L. Castelló 1, Polígono Las Salinas, 08830 Sant Boi de Llobregat, Spain.

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