

Package leaflet: Information for the user

Ibandronic acid Clonmel 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

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1. What Ibandronic acid Clonmel 150 mg is and what it is used for

Ibandronic acid Clonmel 150 mg belongs to a group of medicines called **bisphosphonates**. It contains the active substance ibandronic acid. Ibandronic acid Clonmel 150 mg 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 Clonmel 150 mg 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 Clonmel 150 mg 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 Clonmel 150 mg

DO NOT take Ibandronic acid Clonmel 150 mg

- 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 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.

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 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 (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 Clonmel 150 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 Clonmel 150 mg.

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're taking Ibandronic acid Clonmel 150 mg. Talk to your doctor before taking Ibandronic acid Clonmel 150 mg:

- 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 plain water and/or if you lie down within an hour of taking Ibandronic acid Clonmel 150 mg. If you develop these symptoms, stop taking Ibandronic acid Clonmel 150 mg and tell your doctor straight away (see section 3).

Children and adolescents

Do not give Ibandronic acid Clonmel 150 mg to children or adolescents below 18 years.

Other medicines and Ibandronic acid Clonmel 150 mg

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 Clonmel 150 mg.
- acetylsalicylic acid and other non-steroidal anti-inflammatory medicines (NSAIDs) (including ibuprofen, diclofenac sodium and naproxen) may irritate the stomach and intestine. Bisphosphonates (like Ibandronic acid Clonmel 150 mg) may also do so. So be especially careful if you take painkillers or anti-inflammatories while you're taking Ibandronic acid Clonmel 150 mg.

After swallowing your monthly Ibandronic acid Clonmel 150 mg tablet, wait for 1 hour before taking any other medication, including indigestion tablets, calcium supplements, or vitamins.

Ibandronic acid Clonmel 150 mg with food and drink

Do not take Ibandronic acid Clonmel 150 mg with food. Ibandronic acid Clonmel 150 mg is less effective if it's taken with food.

You can drink plain water but no other drinks.

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 (see section 3).

Take Ibandronic acid Clonmel 150 mg at least 6 hours after you had last had anything to eat, drink or any other medicines or supplements (e.g. products containing calcium (milk), aluminium, magnesium and iron) except water.

After you have taken Ibandronic acid Clonmel 150 mg, please wait for 1 hour before you can have your first food and further drinks (see section 3. How to take Ibandronic acid Clonmel 150 mg).

Pregnancy and breast feeding

Ibandronic acid Clonmel 150 mg 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 Clonmel 150 mg if you're pregnant or breast feeding. If you're breast feeding, you may need to stop in order to take Ibandronic acid Clonmel 150 mg.

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 Clonmel 150 mg has no or negligible effect on your ability to drive and use machines.

Ibandronic acid Clonmel 150 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 medicinal product.

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 Clonmel 150 mg

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 Clonmel 150 mg is one tablet once a month.

Method of administration

It's important to follow these instructions carefully. They are designed to help your Ibandronic acid Clonmel 150 mg tablet reach your stomach quickly, so it's less likely to cause irritation.

- take one Ibandronic acid Clonmel 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 Clonmel 150 mg tablet. Choose the date that best fits your routine.
- take your Ibandronic acid Clonmel 150 mg tablet at least 6 hours after you last had anything to eat or drink except water.
- take your Ibandronic acid Clonmel 150 mg 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 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'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 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 medication you need.

Do not take your tablet at bedtime or before you get up for the day.

Continuing to take Ibandronic acid Clonmel 150 mg

It's important to keep taking Ibandronic acid Clonmel 150 mg every month, as long as your doctor prescribes it for you. After 5 years of using Ibandronic acid Clonmel 150 mg, please consult with your doctor whether you should continue to take Ibandronic acid Clonmel 150 mg.

If you take more Ibandronic acid Clonmel 150 mg than you should

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 Clonmel 150 mg to irritate your oesophagus.

If you forget to take Ibandronic acid Clonmel 150 mg

Do not take a double dose to make up for a forgotten 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 acid Clonmel 150 mg tablets within the same week.

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
- symptoms of low blood calcium levels (hypocalcaemia) including muscle cramps or spasms and/or tingling sensation in the fingers or around the mouth

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:

HPRA Pharmacovigilance

Website: www.hpra.ie

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

5. How to store Ibandronic acid Clonmel 150 mg

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

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

This medicinal product 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 Clonmel 150 mg contains

The active substance is ibandronic acid.

Each tablet contains 150 mg of ibandronic acid (as ibandronic acid sodium monohydrate).

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 Clonmel 150 mg looks like and contents of the pack

Ibandronic acid Clonmel 150 mg tablets are white to off-white, oblong tablets inscribed with “I9BE” on one side and “150” on the other side.

They are available in blister packs of 1, 3, 6, 9 or 12 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturers:

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

Synthon Hispania S.L., C/ Castelló, 1, 08830 Sant Boi de Llobregat, Spain

STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany

Eurogenerics N.V., Heizel Esplanade B22, 1020 Brussels, Belgium

STADA Arzneimittel GmbH, Muthgasse 36, 1190 Wien, Austria

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

Belgium	Ibandronate EG 150 mg filmomhulde tabletten
Bulgaria	Ibandronic acid STADA 150 mg film-coated tablets
Denmark	Ibandronat STADA
Finland	Ibandronat STADA 150 mg tabletti, kalvopäällysteinen
Germany	Ibandronsäure AL 150 mg filmtabletten
Ireland	Ibandronic acid Clonmel 150 mg film-coated tablets
Italy	ACIDO IBANDRONICO EG 150 mg compresse rivestite con film
Luxembourg	Ibandronate EG 150 mg filmomhulde tabletten
Portugal	Ácido Ibandrónico Stada
Romania	Acid Ibandronic STADA, comprimate filmate, 150 mg
Slovak Republic	Ibandronic acid STADA
Spain	Ácido Ibandrónico STADA 150 mg comprimidos recubiertos con película EFG

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