PACKAGE LEAFLET: INFORMATION FOR THE USER

Bonefurbit

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.
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What is in this leaflet:
1. What Bonefurbit is and what it is used for
2. What you need to know before you take Bonefurbit
3. How to take Bonefurbit
4. Possible side effects
5. How to store Bonefurbit
6. Content of the pack and other information

1. What Bonefurbit is and what it is used for

Bonefurbit belongs to a group of medicines called **bisphosphonates**. It contains the active substance ibandronic acid. Bonefurbit 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. Bonefurbit may help lower the chances of breaking bones (fractures). This reduction in fractures was shown for the spine but not for the hip.

Bonefurbit 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 Bonefurbit

Do not take Bonefurbit
- If you are allergic to ibandronic acid, or to 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 Bonefurbit 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 Bonefurbit.

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 Bonefurbit.

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 Bonefurbit. Talk to your doctor before taking Bonefurbit:
- 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 Bonefurbit. If you develop these symptoms, stop taking Bonefurbit and tell your doctor straight away (see section 3).

Children and adolescents
Do not give Bonefurbit to children or adolescents below 18 years.

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

- **Supplements containing calcium, magnesium, iron or aluminium,** as they could possibly influence the effects of Bonefurbit.

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

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

Bonefurbit with food and drink:
Do not take Bonefurbit with food. Bonefurbit is less effective if it's taken with food.

You can drink water but no other drinks.

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

Pregnancy and breast feeding

Bonefurbit is for use only by postmenopausal women and must not be taken by women who could still have a baby.

Do not take Bonefurbit 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's expected that Bonefurbit has no or negligible effect on your ability to drive and use machines.

Bonefurbit 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.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium-free".

3. How to take Bonefurbit

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 Bonefurbit is one tablet once **a month.**

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

Tear and carefully peel off the lidding foil.

Take one Bonefurbit 150mg 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 Bonefurbit tablet. Choose the date that best fits your routine.
- Take your Bonefurbit tablet **at least 6 hours after you last had anything** to eat or drink except water.
- Take your Bonefurbit 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.

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

If you take more Bonefurbit 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 Bonefurbit to irritate your oesophagus.

If you forget to take Bonefurbit
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 you forgot to take your tablets on your chosen day and your next scheduled dose is only 1 to 7 days away…

Never take two Bonefurbit 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've 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've marked on your calendar.

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

Rare (may affect up to 1 in 1000 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 jawbone).
- 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 1000 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, pharmacist or nurse. 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 affects you can help provide more information on the safety of this medicine.

5. How to store Bonefurbit

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 after "EXP". The expiry date refers to the last day of that month.

There are no special storage instructions.

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

6. Contents of the pack and other information

What Bonefurbit contains

- The active substance is ibandronic acid. One tablet contains 150 mg of ibandronic acid (as ibandronate sodium hydrate).
- The other ingredients are:
  tablet core: lactose monohydrate, cellulose microcrystalline, croscarmellose sodium, magnesium stearate, silica colloidal anhydrous
  tablet coat: hydroxypropylcellulose, titanium dioxide (E171), macrogol 6000

What Bonefurbit looks like and contents of the pack

Bonefurbit 150 mg film-coated tablets are white film-coated tablets of oblong shape and scored "LC" on one side.

Bonefurbit 150 mg film-coated tablets is available in pack sizes of 1 and 3 film-coated tablets. The tablets are supplied in blisters containing 1 or 3 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:
Rowa Pharmaceuticals Limited.
Bantry
Co. Cork
Ireland.

Manufacturer:
Laboratorios LICONSA, S.A.
Avda. Miralcampo, Nº 7, Polígono Industrial Miralcampo
19200 Azuqueca de Henares (Guadalajara), SPAIN.

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