

SCHEDULING STATUS

S4

BONIVA® 150 mg, film coated tablets **Ibandronic acid**

Contains sugar: Lactose monohydrate 162,75 mg per tablet

Read all of the leaflet carefully before you start taking BONIVA 150 mg

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse, or other health care provider.
- BONIVA 150 mg has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What BONIVA 150 mg is and what it is used for
2. What you need to know before you take BONIVA 150 mg
3. How to take BONIVA 150 mg
4. Possible side effects
5. How to store BONIVA 150 mg
6. Contents of the pack and other information

1. What BONIVA 150 mg is and what it is used for

BONIVA 150 mg belongs to a group of medicines called bisphosphonates. It does not contain hormones.

BONIVA 150 mg is prescribed for you to treat osteoporosis. Osteoporosis is a thinning and weakening of the bones, which is common in women after menopause. At menopause, a woman's ovaries stop producing the female hormone, estrogen, which helps to keep her skeleton healthy.

Other things that can increase the risk of osteoporosis 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.

BONIVA 150 mg prevents loss of bone from osteoporosis and helps to rebuild bone. Therefore, BONIVA 150 mg 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. What you need to know before you take or use BONIVA 150 mg

Do not take BONIVA 150 mg

- If you are hypersensitive (allergic) to ibandronic acid, or any of the other ingredients of BONIVA 150 mg (listed in section 6.1).
- If you have, or believe that you may have, low blood calcium, please consult your doctor.
- If your kidneys are not functioning normally.
- 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 up to an hour at a time.

Do not give BONIVA 150 mg to children or adolescents.

Warnings and precautions

Some people need to be especially careful while they're taking BONIVA 150 mg.

Tell your doctor:

- If you have any disturbances of mineral metabolism (such as vitamin D deficiency).
- If you have any problems with your mouth or teeth such as poor dental health, gum disease, or a planned tooth extraction or you don't receive routine dental care.
- If you have previously been treated with a bisphosphonate (used to treat or prevent bone disorders).
- If you are taking medicines called corticosteroids (such as prednisolone or dexamethasone).
- If you have cancer.
- If you have ear problems or ear infections.
- If you have pain in the thigh, hip, groin, arms or legs.

Your doctor may ask you to undergo a dental examination before starting treatment with BONIVA 150 mg.

You should maintain good oral hygiene and receive routine dental check-ups while being treated with BONIVA 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.

You should take calcium and vitamin D supplements while receiving BONIVA 150 mg.

If you have ever had problems with your oesophagus (the tube connecting your mouth to your stomach). Problems in your oesophagus might give you symptoms including severe pain in the chest, severe pain after swallowing food and/or drink, severe nausea, or vomiting. If you develop these symptoms, speak to your doctor straight away.

Children and adolescents

BONIVA 150 mg must not be used in children or adolescents below 18 years.

Other medicines and BONIVA 150 mg

Always tell your health care provider if you are taking any other medicines. (This includes all complementary or traditional medicines.)

Mention anything you're taking which you bought over the counter, without a prescription; or any supplements containing calcium, magnesium, iron or aluminium.

Aspirin and other non-steroidal anti-inflammatory medicines (NSAIDs) may irritate the stomach and intestine. Bisphosphonates (like BONIVA 150 mg) may also do so. So be especially careful

if you take painkillers or anti-inflammatories while you're taking BONIVA 150 mg. (NSAIDs include ibuprofen, diclofenac sodium and naproxen.)

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

BONIVA 150 mg with food and drink

Do not take BONIVA 150 mg with food and drink (except plain water). BONIVA 150 mg is less effective if it is taken with food.

Pregnancy, breastfeeding and fertility

Do not take BONIVA 150 mg if you're pregnant or breastfeeding. If you're breastfeeding, you may need to stop in order to take BONIVA 150 mg.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other health care provider for advice before taking BONIVA 150 mg.

Driving and using machines

You can drive and use machines. It's very unlikely that BONIVA 150 mg will affect your ability to drive and use machines.

BONIVA 150 mg contains lactose monohydrate and macrogol

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking BONIVA 150 mg.

Macrogol may cause stomach upset and diarrhoea.

3. How to take BONIVA 150 mg

Do not share medicines prescribed for you with any other person.

Always take BONIVA 150 mg exactly as your doctor or pharmacist has told you. If you are not sure about anything, ask your doctor or pharmacist.

The usual dose of BONIVA 150 mg is one tablet once a month.

Taking your monthly tablet

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

- Take one BONIVA 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 BONIVA 150 mg tablet. Choose the date that best fits your routine.
- Take your BONIVA 150 mg tablet at least 6 hours after you last had anything to eat or drink except plain water.
- Take your BONIVA 150 mg tablet
 - after you first get up for the day, and
 - before you have anything else 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 okay 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 BONIVA 150 mg

It's important to keep taking BONIVA 150 mg every month, as long as your doctor prescribes it for you. BONIVA 150 mg can treat osteoporosis only as long as you keep taking it.

You should also take calcium and vitamin D supplements, as recommended by your doctor.

If you take more BONIVA 150 mg than you should

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

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 BONIVA 150 mg to irritate your oesophagus.

If you forget to take BONIVA 150 mg

If you forget to take your tablet in the morning of your chosen day, do not take a tablet later in the day. Instead, follow these instructions:

When is your next scheduled dose due?

If your next scheduled dose is more than 7 days away (or if your missed dose is less than 3 weeks late)

- take one tablet the next morning after the day you remember.
- then, go back to taking your tablets on the scheduled days you've marked on your calendar.

If your next scheduled dose is only 1 to 7 days away (or if your missed dose is more than 3 weeks late)

- wait until your next scheduled dose is due and take it as normal.
- then, go back to taking your tablets on the scheduled days you've marked on your calendar.

Never take two BONIVA 150 mg tablets within the same week.

4. Possible side effects

BONIVA 150 mg can have side effects.

Not all side effects reported for BONIVA 150 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BONIVA 150 mg, please consult your health care provider for advice.

If any of the following happens, tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,
- sores, blistering and peeling of the skin.

These are all very serious side effects. If you have them, you may have had a serious reaction to BONIVA 150 mg. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- low blood calcium levels (hypocalcaemia), symptoms include muscle cramps and/or tingling sensation in the fingers or lips,
- pain and inflammation of the eye(s),
- irritation of the oesophagus, symptoms include severe pain in the chest, severe pain after swallowing food or drink, severe nausea, or vomiting,
- a crack or break (fracture) of the thigh bone or other bones in your arms or legs, symptoms include pain, weakness or discomfort in your thigh, hip, groin, arms or legs,
- pain, swelling and sores in the mouth,
- ear pain, a feeling of fullness in the ear, loss of hearing or a ringing sensation in the ears.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Common side effects:

- headache,
- heartburn, indigestion, diarrhoea, stomach ache, nausea,
- pain in the muscles or joints, muscle cramps, stiffness of the muscles
- flu-like symptoms (aches, pain, feeling of discomfort).

Uncommon side effects:

- coughing, breathlessness, wheezing or tight chest,
- dizziness,
- vomiting, passing of wind or having gas,
- back pain,
- tiredness.

Rare side effects:

- inflammation of the duodenum (first section of the bowel), symptoms include burning or cramping of the stomach, feeling bloated, lack of appetite or tar-coloured or dark stools.

If you notice any side effects not mentioned in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of BONIVA 150 mg.

5. How to store BONIVA 150 mg

- Store all medicines out of reach of children.
- Store at or below 30 °C.
- Keep in the original package until required for use.
- Don't use after the expiry date stated on the carton.
- Do not store in a bathroom.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information**What BONIVA 150 mg contains**

The active ingredient is ibandronic acid.

Each film-coated tablet contains 150 mg ibandronic acid.

The other ingredients are:

Tablet core: colloidal anhydrous silica, crospovidone, lactose monohydrate, microcrystalline cellulose, povidone and stearic acid. Film-coating: hypromellose, macrogol 6 000, talc and titanium dioxide.

What BONIVA 150 mg looks like and contents of the pack

White to off-white film-coated tablets, of oblong shape, marked "BNVA" on one side and "150" on the other side.

BONIVA 150 mg is available in pack sizes of 1 or 3 tablets in aluminium-aluminium or PVC/PVDC (duplex)-aluminium blisters.

Not all pack sizes and/or pack types may be marketed.

Holder of Certificate of Registration

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