

1.3.1 Package Leaflet

Package leaflet: Information for the user

Bonviva 3 mg solution for injection ibandronic acid

Read all of this leaflet carefully before you start using 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, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Bonviva is and what it is used for
2. What you need to know before you receive Bonviva
3. How to receive Bonviva
4. Possible side effects
5. How to store Bonviva
6. Content of the pack and other information

1. What Bonviva is and what it is used for

Bonviva belongs to a group of medicines called bisphosphonates. It contains the active substance ibandronic acid.

Bonviva 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. Bonviva may help lower the chances of breaking bones (fractures). This reduction in fractures was shown for the spine but not for the hip.

Bonviva 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 cigarettes, 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 other weight-bearing exercise
- not smoking and not drinking too much alcohol

2. What you need to know before you receive Bonviva

Do not receive Bonviva

- **if you have, or had in the past, low blood calcium.** Please consult your doctor
- if you are allergic to ibandronic acid or any of the other ingredients of this medicine (listed in section 6)

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 Bonviva 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.

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 Ibandronate. 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.

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 Bonviva.

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 Bonviva.

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 patients need to be especially careful when using Bonviva. Talk to your doctor before receiving Bonviva:

- If you have or have ever had kidney problems, kidney failure or have needed dialysis, or if you have any other disease that may affect your kidneys
- If you have any disturbance of mineral metabolism (such as vitamin D deficiency)
- You should take calcium and vitamin-D supplements while receiving Bonviva. If you are unable to do so, you should inform your doctor
- If you have heart problems and the doctor recommended to limit your daily fluid intake.

Cases of serious, sometimes fatal allergic reaction have been reported in patients treated with intravenous ibandronic acid. If you experience one of the following symptoms, such as shortness of breath/difficulty breathing, tight feeling in throat, swelling of tongue, dizziness, feeling of loss of consciousness, redness or swelling of face, body rash, nausea and vomiting, you should immediately alert your doctor or nurse (see section 4).

Children and adolescents

Bonviva must not be used in children or adolescents below 18 years.

Other medicines and Bonviva

Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding

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

Do not take Bonviva 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 Bonviva has no or negligible effect on your ability to drive and use machines.

Bonviva contains less than 1 mmol sodium (23 mg) per dose (3 ml), i.e. essentially “sodium-free”.

3. How to receive Bonviva

The recommended dose of Bonviva for the intravenous injection is 3 mg (1 pre-filled syringe) once every 3 months.

The injection should be given into the vein by a physician or qualified/trained health care worker. Do not administer the injection to yourself.

The solution for injection must be administered into a vein only, and not anywhere else in the body.

Continuing to receive Bonviva

To get the most benefit from the treatment it is important to continue receiving the injections every 3 months for as long as your doctor prescribes it for you. Bonviva can treat osteoporosis only for as long as you keep receiving the treatment, even though you will not be able to see or feel a difference. After 3-5 years of receiving Bonviva, please consult with your doctor whether you should continue to receive Bonviva.

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

If too much Bonviva is given

You may develop low levels of calcium, phosphorus or magnesium in the blood. Your doctor may take steps to correct such changes and may give you an injection containing these minerals.

If a dose of Bonviva is missed

You should arrange an appointment to get the next injection as soon as possible. After that, go back to getting the injections every 3 months from the date of the most recent injection.

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

- 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 1000 people):

- itching, swelling of your face, lips, tongue and throat, with difficulty breathing.
- persistent eye pain and inflammation (if prolonged)
- 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 10000 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 (see section 2).
- severe adverse skin reactions

Other possible side effects

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

- headache
- stomach pain (such as gastritis) or tummy pain, indigestion, nausea, having diarrhoea (loose bowels) or constipation
- pain in your muscles, joints, or back
- feeling tired and exhausted
- 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)

- inflammation of a vein
- pain or injury at the injection site
- bone pain
- feeling weak
- asthma attacks

Rare (may affect up to 1 in 1000 people):

- hives

Reporting of side effects

If you get any side effects, talk to your doctor, nurse 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 Bonviva

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

This medicinal product does not require any special storage conditions.

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

The person giving the injection should throw away any unused solution and put the used syringe and injection needle into an appropriate disposal container.

6. Content of the pack and other information

What Bonviva contains

- The active substance is ibandronic acid. One pre-filled syringe contains 3 mg of ibandronic acid in 3 ml of solution (as sodium monohydrate).

Bonviva 3mg/3mL Solution for injection
PLGB 43252/0023

Atnahs Pharma UK Limited

- The other ingredients are sodium chloride, acetic acid, sodium acetate trihydrate and water for injections.

What Bonviva looks like and contents of the pack

Bonviva 3 mg solution for injection in pre-filled syringes is a clear colourless solution. Each pre-filled syringe contains 3 ml of solution. Bonviva is available in packs of 1 pre-filled syringe and 1 injection needle or 4 pre-filled syringes and 4 injection needles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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This information is intended for healthcare professionals only:

INFORMATION FOR THE HEALTHCARE PROFESSIONALS

Please see the Summary of Product Characteristics for more information.

Administration of Bonviva 3 mg solution for injection in pre-filled syringe:

Bonviva 3 mg solution for injection in pre-filled syringe should be injected intravenously over a period of 15 - 30 seconds.

The solution is irritant, therefore strict adherence to the intravenous route of administration is important. If you inadvertently inject into the tissues around the vein, patients may experience local irritation, pain and inflammation at the injection site.

Bonviva 3 mg solution for injection in pre-filled syringe **must not** be mixed with calcium-containing solutions (such as Ringer-Lactate solution, calcium heparin) or other intravenously administered medicinal products. Where Bonviva is administered via an existing intravenous infusion line, the intravenous infusate should be restricted to either isotonic saline or 50 mg/ml (5 %) glucose solution.

Missed dose:

If a dose is missed, the injection should be administered as soon as convenient. Thereafter, injections should be scheduled every 3 months from the date of the last injection.

Overdose:

No specific information is available on the treatment of overdosage with Bonviva.

Based on knowledge of this class of compounds, intravenous overdosage may result in hypocalcaemia, hypophosphataemia, and hypomagnesaemia, which can cause paraesthesia. In severe cases intravenous infusion of appropriate doses of calcium gluconate, potassium or sodium phosphate, and magnesium sulfate, may be needed.

General advice:

Bonviva 3 mg solution for injection in pre-filled syringe like other bisphosphonates administered intravenously, may cause a transient decrease in serum calcium values.

Hypocalcaemia and other disturbances of bone and mineral metabolism should be assessed and effectively treated before starting Bonviva injection therapy. Adequate intake of calcium and vitamin D is important in all patients. All patients must receive supplemental calcium and vitamin D.

Patients with concomitant diseases, or who use medicinal products which have a potential for undesirable effects on the kidney, should be reviewed regularly in line with good medical practice during treatment.

Any unused solution for injection, syringe and injection needle should be disposed of in accordance with local requirements.