

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.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

In this leaflet:

1. What Bonviva is and what it is used for
2. Before you receive Bonviva
3. How to receive Bonviva
4. Possible side effects
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6. Further information

1. WHAT BONVIVA IS AND WHAT IT IS USED FOR

Bonviva belongs to a group of medicines called bisphosphonates. It contains ibandronic acid. It does not contain hormones.

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 3 mg solution for injection in pre-filled syringes is a solution for intravenous injection by a health care professional. **Do not inject Bonviva yourself.**

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

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.

Bonviva prevents loss of bone from osteoporosis, thus helping to rebuild lost bone. Therefore, Bonviva makes bones 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 other weight-bearing exercise, not smoking and not drinking too much alcohol.

2. 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 (hypersensitive) to ibandronic acid or any of the other ingredients in Bonviva injection

Take special care with Bonviva

Some patients need to be especially careful when using Bonviva. Tell your doctor:

- 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 are under dental treatment or will undergo dental surgery, tell your dentist that you are being treated with Bonviva.

Taking other medicines

Tell your doctor, nurse or pharmacist if you are taking, or have recently taken, any other medicines. Mention to your doctor, nurse or pharmacist anything you are taking which you bought over the counter, without a prescription.

Pregnancy and breast-feeding

You should not be given Bonviva if you are pregnant, or if there is a possibility you may become pregnant. If you are breast-feeding, you will need to stop breast-feeding in order to receive Bonviva. Ask your doctor or pharmacist for advice before taking any medicines.

Driving and using machines

You can drive and use machines as it's very unlikely that Bonviva will affect your ability to drive and use machines.

Important information about some of the ingredients of Bonviva

This medicinal product 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.

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, Bonviva 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:

- rash, itching, swelling of your face, lips, tongue and throat, with difficulty breathing. You may be having an allergic reaction to the medicine.
- severe pain in the chest, severe pain after swallowing food or drink, severe nausea, or vomiting.
- flu-like symptoms (if any effects become troublesome or last more than a couple of days).
- pain or sore in your mouth or jaw
- eye pain and inflammation (if prolonged)

Other possible side effects

Common (affects less than 1 in 10 people)

- headache
- heartburn, stomach pain (such as “gastroenteritis” or “gastritis”), indigestion, nausea, having diarrhoea or constipation
- rash
- pain or stiffness in your muscles, joints, or back
- flu-like symptoms (including fever, shaking and shivering, feeling of discomfort, fatigue, bone pain and aching muscles and joints)
- fatigue

Uncommon (affects less than 1 in 100 people)

- bone pain
- feeling weak
- dizziness
- flatulence
- inflammation of a vein and pain or injury at the injection site

Rare (affects less than 1 in 1000 people):

- hypersensitivity reaction; swelling of the face, lips and mouth (see allergy)
- itching
- eye pain or inflammation

Very rare (affects less than 1 in 10000 people)

- a condition involving exposed bone in the mouth called “osteonecrosis of the jaw”.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE BONVIVA

Keep out of the reach and sight of children.

This medicinal product does not require any special storage conditions.

Do not use Bonviva 3 mg solution for injection in pre-filled syringes 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. FURTHER INFORMATION

What Bonviva 3 mg solution for injection in pre-filled syringes contains

- The active substance is ibandronic acid. One pre-filled syringe contains 3 mg of ibandronic acid in 3 ml of solution (as 3.375 mg of ibandronic acid, monosodium salt, monohydrate).
- The other ingredients are sodium chloride, acetic acid, sodium acetate trihydrate and water for injections

What Bonviva 3 mg solution for injection in pre-filled syringes 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

Roche Registration Limited
6 Falcon Way
Shire Park
Welwyn Garden City
AL7 1TW
United Kingdom

Manufacturer

Roche Pharma AG
Emil-Barell-Strasse 1
D-79639 Grenzach-Wyhlen
Germany

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

België/Belgique/Belgien

N.V. Roche S.A.
Tél/Tel: +32 (0) 2 525 82 11

Luxembourg/Luxemburg

(Voir/siehe Belgique/Belgien)

България

Рош България ЕООД
Тел: +359 2 818 44 44

Česká republika

Roche s. r. o.
Tel: +420 - 2 20382111

Danmark

Roche a/s
Tlf: +45 - 36 39 99 99

Deutschland

Roche Pharma AG
Tel: +49 (0) 7624 140

Eesti

GlaxoSmithKline Eesti OÜ
Tel: + 372 - 6 676 900
estonia@gsk.com

Ελλάδα

Roche (Hellas) A.E.
Τηλ: +30 210 61 66 100

España

Roche Farma S.A.
Tel: +34 - 91 324 81 00

France

Roche
Tél: +33 (0) 1 46 40 50 00

Ireland

Roche Products (Ireland) Ltd.
Tel: +353 (0) 1 469 0700

Ísland

Roche a/s
c/o Icepharma hf
Tel: +354 540 8000

Italia

Roche S.p.A.
Tel: +39 - 039 2471

Κύπρος

GlaxoSmithKline (Cyprus) Ltd
Τηλ: +357 - 22 39 70 00

Latvija

GlaxoSmithKline Latvia SIA
Tel: +371 -6 7312687

Magyarország

Roche (Magyarország) Kft.
Tel: +36 - 23 446 800

Malta

GlaxoSmithKline Malta
Tel: + 356 21 238131

Nederland

Roche Nederland B.V.
Tel: +31 (0) 348 438050

Norge

Roche Norge AS
Tlf: +47 - 22 78 90 00

Österreich

Roche Austria GmbH
Tel: +43 (0) 1 27739

Polska

Roche Polska Sp.z o.o.
Tel: +48 - 22 345 18 88

Portugal

Roche Farmacêutica Química, Lda
Tel: +351 - 21 425 70 00

România

Roche România S.R.L.
Tel: +40 21 206 47 01

Slovenija

Roche farmacevtska družba d.o.o.
Tel: +386 - 1 360 26 00

Slovenská republika

Roche Slovensko, s.r.o.
Tel: +421 - 2 52638201

Suomi/Finland

Roche Oy
Puh/Tel: +358 (0) 10 554 500

Sverige

Roche AB
Tel: +46 (0) 8 726 1200

United Kingdom

Roche Products Ltd.
Tel: +44 (0) 1707 366000

Lietuva

UAB „GlaxoSmithKline Lietuva“

Tel: +370 5 2 649000

info.lt@gsk.com

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Detailed information on this medicine is available on the European Medicines Agency web site:

<http://www.ema.europa.eu/>