

Package leaflet: Information for the user

Bonviva
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:

**Planning when to take Bonviva
with peel-off stickers for your personal calendar**

1. What Bonviva is and what it is used for
2. What you need to know before you take Bonviva
3. How to take 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, 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 Bonviva

Do not take Bonviva

- 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 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.

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 people need to be especially careful while they're taking Bonviva. Talk to your doctor before taking Bonviva:

- 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 Bonviva. If you develop these symptoms, stop taking Bonviva and tell your doctor straight away (see section 3).

Children and adolescents

Do not give Bonviva to children or adolescents below 18 years.

Other medicines and Bonviva

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

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

Bonviva with food and drink:

Do not take Bonviva with food. Bonviva is less effective if it's taken with food.

You can drink water but no other drinks

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

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 lactose.

If you have been told by your doctor that you cannot tolerate or digest some sugars (e.g. if you have a galactose intolerance, the Lapp lactase deficiency or have problems with glucose-galactose absorption), talk to your doctor before taking this medicine.

3. How to take Bonviva

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose of Bonviva is one tablet once a month.

Taking your monthly tablet

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

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

- Take your Bonviva 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 Bonviva

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

If you take more Bonviva 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 Bonviva to irritate your oesophagus.

If you forget to take Bonviva

- 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 tablet on your chosen day and your next scheduled dose is only 1 to 7 days away...**

Never take two Bonviva 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

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 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

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below).

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

Ireland

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

Malta

ADR Reporting

Website: www.medicinesauthority.gov.mt/adrportal

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

5. How to store Bonviva

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

There are no special storage instructions.

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.

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 Bonviva contains

- The active substance is ibandronic acid. One tablet contains 150 mg of ibandronic acid (as sodium monohydrate).
- The other ingredients are:

tablet core: lactose monohydrate, povidone, cellulose microcrystalline, crospovidone, stearic acid purified, silica colloidal anhydrous

tablet coat: hypromellose, titanium dioxide (E 171), talc, macrogol 6000

What Bonviva looks like and contents of the pack

Bonviva tablets are white to off white, of oblong shape and marked “BNVA” on one side, and “150” on the other side. The tablets are supplied in blisters containing 1 or 3 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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 medicine, 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

Lietuva

UAB “Roche Lietuva”
Tel: +370 5 2546799

България

Рош България ЕООД
Тел: +359 2 818 44 44

Luxembourg/Luxemburg

(Voir/siehe Belgique/Belgien)

Česká republika

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

Magyarország

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

Danmark

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

Malta

(See United Kingdom)

Deutschland

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

Nederland

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

Eesti

Roche Eesti OÜ
Tel: + 372 - 6 177380

Norge

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

Ελλάδα

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

Österreich

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

España

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

Polska

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

France
Roche
Tél: +33 (0) 1 47 61 40 00

Hrvatska
Roche d.o.o
Tel: +385 1 4722 333

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

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

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

Κύπρος
Γ.Α.Σταμάτης & Σια Λτδ.
Τηλ: +357 - 22 76 62 76

Latvija
Roche Latvija SIA
Tel: +371 -6 7039831

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

This leaflet was last revised in April 2016.

Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>.

REMINDER STICKERS TEXT

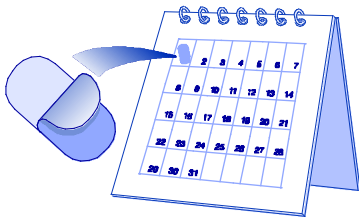
PLANNING WHEN TO TAKE BONVIVA

The dose of Bonviva is one tablet once a month. Choose one day of the month that will be easy to remember:

- either the same date (such as the 1st of each month)
- or the same day (such as the first Sunday of each month).

Use the peel-off stickers below to mark the dates on your calendar.

Once you've taken your tablet, put a tick in the box on the sticker.



PEEL-OFF STICKERS FOR YOUR PERSONAL CALENDAR

Monthly tablet Monthly tablet Monthly tablet

Bonviva Bonviva Bonviva

It's important to keep taking Bonviva every month.