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**What BONMAX TABLET is used for**  
BONMAX is used to treat and prevent osteoporosis in postmenopausal women. BONMAX reduces the risk of back bone fractures in women with postmenopausal osteoporosis. A reduction in the risk of hip fractures has not been shown.

Your doctor may have prescribed BONMAX for another reason. Ask your doctor if you have any questions about why BONMAX has been prescribed for you.

## How BONMAX TABLET works

The name of your medicine is BONMAX TABLET. It contains the active ingredient Raloxifene hydrochloride.

BONMAX belongs to a group of non-hormonal medicines called Selective Oestrogen Receptor Modulators (SERMs). When a woman reaches menopause, the level of the female sex hormone oestrogen goes down. BONMAX mimics some of the helpful effects of oestrogen after the menopause. Osteoporosis is a disease that causes your bones to become thin and fragile - this disease is especially common in women after the menopause. Although it may have no symptoms at first, osteoporosis makes you more likely to break bones, especially in your spine, hips and wrists and may cause back pain, loss of height and a curved back. Raloxifene decreases resorption of bone and reduces biochemical markers of bone turnover to the premenopausal range.

## Before you use BONMAX TABLET

- When you must not use it
- If you are being treated or have been treated for blood clots in the legs (deep vein thrombosis), in the lungs (pulmonary embolism) or in the eyes (retinal vein thrombosis).
- If you are allergic (hypersensitive) to raloxifene or any of the other ingredients of this medicine (see section **Production description**).
- If there is still a possibility that you can get pregnant, BONMAX could harm your unborn child.

## Pregnancy and lactation

Do not take BONMAX TABLET if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take BONMAX TABLET if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it
- Talk to your doctor or pharmacist before you take BONMAX.
- If you are immobilised for some time such as being wheel-chair bound, needing to be admitted to a hospital or having to stay in bed while recovering from an operation or an unexpected illness as these may increase your risk of blood clots (deep vein thrombosis, pulmonary embolism or retinal vein thrombosis).
- If you have had a cerebrovascular accident (e.g. stroke), or if your doctor has told you that you are at high risk of having one.
- If you are receiving oral oestrogen therapy.
- If you have liver disease [e.g. cirrhosis (a liver disease characterised by scarring of the liver with loss of normal liver cells), mild hepatic impairment, or cholestatic jaundice (jaundice resulted from abnormal bile flow)]
- If you have severe kidney problems.
- If you have any unexplained vaginal bleeding. This must be investigated by your doctor.
- If you have active uterine cancer or suffering from breast cancer, as there is insufficient experience of

BONMAX use in women with this disease.

- If you are breast-feeding.

BONMAX lowers total cholesterol and LDL ("bad") cholesterol. In general, it does not change triglycerides or HDL ("good") cholesterol. However, if you have taken oestrogen in the past and had extreme elevations in triglycerides, you should talk to your doctor before taking BONMAX.

## - Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

- If you are taking digitalis medicines for your heart (e.g. digoxin) or anticoagulants like warfarin to thin your blood, your doctor may need to adjust your dose of these medicines.
- If you are taking cholestyramine which is mainly used as lipid-lowering medicine, because BONMAX may not work as well.
- If you are taking nonsteroidal anti-inflammatory drugs (NSAIDs) such as indomethacin, naproxen, ibuprofen.

## How to use BONMAX TABLET

- How much to use
- The recommended dosage is one BONMAX 60mg tablet a day. You may take it with or without food

The doctor may also advise you to take calcium and vitamin D supplements.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

## - When to use it

Swallow the tablet whole. If you wish you may take a glass of water with it. Do not break or crush the tablet before taking it. A broken or crushed tablet may taste bad and there is a possibility that you will receive an incorrect dose.

It does not matter what time of day you take your tablet but taking the tablet at the same time each day will help you remember to take it.

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking BONMAX TABLET for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take more BONMAX than you should you could have leg cramps and dizziness.

**While you are using it**

- Things you must do

BONMAX is for use only by postmenopausal women and must not be taken by women who could still have a baby. BONMAX could harm your unborn child.

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking BONMAX TABLET.

Tell your doctor immediately if you become pregnant while taking BONMAX TABLET.

Make sure you are taking enough calcium and Vitamin D in your diet. Your doctor, pharmacist, or dietitian

can tell you what foods you should eat, and whether you should take a supplement.

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.

- Things you must not do

• Do not stop taking the medicine unless advised by your doctor. It is important that you continue taking BONMAX for as long as your doctor prescribes the medicine. BONMAX can treat or prevent your osteoporosis only if you continue to take the tablets.

• Do not take any new medicines without consulting your doctor.

• Do not give BONMAX TABLET to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

• **BONMAX contains lactose**

If you have been told by your doctor that you have an intolerance to lactose, a type of sugar, contact your doctor before taking this medicinal product.

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

**Side effects**

The majority of side effects seen with BONMAX have been mild.

Tell your doctor if you notice any of the following side effects and they worry you:

- Hot flushes
- Leg cramps

Tell your doctor immediately or go to the Accident and Emergency Department at your nearest hospital if you notice any of the following:

- Symptoms of allergic reaction such as skin rashes, itching, and shortness of breath.
- Severe pain or swelling on hands, feet and legs (peripheral oedema).
- Increased risk of blood clots in the eyes (retinal vein thrombosis).
- Skin around the vein is red and painful (superficial vein thrombophlebitis).
- Blood clot in an artery (for example stroke, including an increased risk of dying from stroke).

Like all medicines, BONMAX TABLET can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers → Reporting).

**Storage and Disposal of BONMAX TABLET**

- Storage

- Keep this medicine out of the sight and reach of children.
- Store below 25°C.
- Do not use after the expiry date which is stated on the pack.
- Store in the original package. Do not freeze.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**Product Description**

- What it looks like

**BONMAX TABLET**

Light yellow coloured, round, biconvex film coated tablets with breakline on one side and plain on other side.

Blister packs of 70 tablets.  
(10x7's/strip).

- Ingredients

Each tablet contains:

- Active ingredient(s)

Raloxifene hydrochloride 60mg

- Inactive ingredients

Croscarmellose Sodium, Povidone K-30, Magnesium Stearate, Polyethylene Glycol 6000, Ferric Oxide, Titanium Dioxide, Lactose Monohydrate, Polysorbate 80, Hydroxypropyl Methylcellulose (6cps), Talc.

- MAL number(s):

MAL06091394A

**Manufacturer**

Cadila Healthcare Limited  
Sarkhej-Bavia N.H. No.8 A,  
Moraiya, Tal: Sanand,  
Dist: Ahmedabad 382 210  
INDIA

**Product Registration Holder**

**THE ZYFAS MEDICAL CO**

No.7, Jalan Molek 3/10  
Taman Molek  
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Johor

**Date of revision**

27/08/2015

**Serial Number**

BPFK(R4/1)270815/00288