

- To facilitate delivery to the stomach, and thus reduce the potential for esophageal irritation, BONIVA tablets should be swallowed whole with a full glass of plain water (6 to 8 oz) while the patient is standing or sitting in an upright position. Patients should not lie down for 60 minutes after taking BONIVA.
- Patients should not eat, drink anything except for water, or take other medications for 60 minutes after taking BONIVA.
- Plain water is the only drink that should be taken with BONIVA. Note that some mineral waters may have a higher concentration of calcium and therefore should not be used.
- Patients should not chew or suck the tablet because of a potential for oropharyngeal ulceration.
- The BONIVA 2.5 mg tablet should be taken at the same time each day.
- If a once-daily dose is missed, the patient should be instructed to skip that dose and return to their normal schedule the next day.
- The patient must not take two 2.5 mg tablets within the same day.
- The BONIVA 150 mg tablet should be taken on the same date each month (i.e., the patient's BONIVA day).
- The patient must not take two 150 mg tablets within the same week.
- If the once-monthly dose is missed, and the patient's next scheduled BONIVA day is more than 7 days away, the patient should be instructed to take one BONIVA 150 mg tablet in the morning following the date that it is remembered (*see DOSAGE AND ADMINISTRATION [2.3]*). The patient should then return to taking one BONIVA 150 mg tablet every month in the morning of their chosen day, according to their original schedule.
- If the once-monthly dose is missed, and the patient's next scheduled BONIVA day is only 1 to 7 days away, the patient must wait until the subsequent month's scheduled BONIVA day to take their tablet. The patient should then return to taking one BONIVA 150 mg tablet every month in the morning of their chosen day, according to their original schedule.

Patients should receive supplemental calcium and vitamin D if dietary intake is inadequate. Intake of supplemental calcium and vitamin D should be delayed for at least 60 minutes following oral administration of BONIVA in order to maximize absorption of BONIVA.

Physicians should be alert to signs or symptoms signaling a possible esophageal reaction during therapy, and patients should be instructed to discontinue BONIVA and seek medical attention if they develop symptoms of esophageal irritation such as new or worsening dysphagia, pain on swallowing, retrosternal pain, or heartburn.

17.2 FDA-Approved Medication Guide

Read the Medication Guide that comes with BONIVA before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking with your doctor about your medical condition or your treatment. Talk to your doctor if you have any questions about BONIVA.

What is the most important information I should know about BONIVA?

BONIVA can cause serious side effects including:

1. Esophagus problems
2. Low calcium levels in your blood (hypocalcemia)
3. Bone, joint or muscle pain
4. Severe jaw bone problems (osteonecrosis)
5. Unusual thigh bone fractures

1. Esophagus problems.

Some people who take BONIVA may develop problems in the esophagus (the tube that connects the mouth and the stomach). These problems include irritation, inflammation, or ulcers of the esophagus which may sometimes bleed.

- **It is important that you take BONIVA exactly as prescribed to help lower your chance of getting esophagus problems (see the section "How should I take BONIVA?").**

- **Stop taking BONIVA and call your doctor right away if you get chest pain, new or worsening heartburn, or have trouble or pain when you swallow.**

2. Low calcium levels in your blood (hypocalcemia).

BONIVA may lower the calcium levels in your blood. If you have low blood calcium before you start taking BONIVA, it may get worse during treatment. Your low blood calcium must be treated before you take BONIVA. Most people with low blood calcium levels do not have symptoms, but some people may have symptoms. Call your doctor right away if you have symptoms of low blood calcium such as:

- Spasms, twitches, or cramps in your muscles
- Numbness or tingling in your fingers, toes, or around your mouth

Your doctor may prescribe calcium and vitamin D to help prevent low calcium levels in your blood, while you take BONIVA. Take calcium and vitamin D as your doctor tells you to.

3. Bone, joint, or muscle pain.

Some people who take BONIVA develop severe bone, joint, or muscle pain.

4. Severe jaw bone problems (osteonecrosis).

Severe jaw bone problems may happen when you take BONIVA. Your doctor may examine your mouth before you start BONIVA. Your doctor may tell you to see your dentist before you start BONIVA. It is important for you to practice good mouth care during treatment with BONIVA.

5. Unusual thigh bone fractures.

Some people have developed unusual fractures in their thigh bone. Symptoms of a fracture may include new or unusual pain in your hip, groin, or thigh.

Call your doctor right away if you have any of these side effects.

What is BONIVA?

BONIVA is a prescription medicine used to treat or prevent osteoporosis in women after menopause. BONIVA helps increase bone mass and helps reduce the chance of having a spinal fracture (break).

It is not known how long BONIVA works for the treatment and prevention of osteoporosis. You should see your doctor regularly to determine if BONIVA is still right for you.

It is not known if BONIVA is safe and effective in children.

Who should not take BONIVA?

Do not take BONIVA if you:

- Have certain problems with your esophagus, the tube that connects your mouth with your stomach
- Cannot stand or sit upright for at least 60 minutes
- Have low levels of calcium in your blood
- Are allergic to BONIVA or any of its ingredients. A list of ingredients is at the end of this leaflet

What should I tell my doctor before taking BONIVA?

Before you start BONIVA, be sure to talk to your doctor if you:

- Have problems with swallowing
- Have stomach or digestive problems
- Have low blood calcium
- Plan to have dental surgery or teeth removed
- Have kidney problems
- Have been told you have trouble absorbing minerals in your stomach or intestines (malabsorption syndrome)

Reference ID: 2895714

- Are pregnant, or plan to become pregnant. It is not known if BONIVA can harm your unborn baby.
- Are breast-feeding or plan to breast-feed. It is not known if BONIVA passes into your milk and may harm your baby.

Tell your doctor and dentist about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Certain medicines may affect how BONIVA works.

Especially tell your doctor if you take:

- antacids
- aspirin
- Nonsteroidal Anti-Inflammatory (NSAID) medicines

Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist each time you get a new medicine.

How should I take BONIVA?

- Take BONIVA exactly as your doctor tells you.
- **BONIVA works only if taken on an empty stomach.**
- Take 1 BONIVA tablet, **after** you get up for the day and **before** taking your first food, drink, or other medicine.
- Take BONIVA while you are sitting or standing.
- **Do not chew or suck on a tablet of BONIVA.**
- Swallow BONIVA tablet with a full glass (6-8 oz) of plain water only.
- Do **not** take BONIVA with mineral water, coffee, tea, soda, or juice.

After swallowing BONIVA tablet, wait at least 60 minutes:

- Before you lie down. You may sit, stand or walk, and do normal activities like reading.
- Before you take your first food or drink except for plain water.
- Before you take other medicines, including antacids, calcium, and other supplements and vitamins.

Do not lie down for at least 60 minutes after you take BONIVA and do not eat your first food of the day for at least 60 minutes after you take BONIVA.

If you miss a dose of BONIVA, do not take it later in the day. Call your doctor for instructions.

If you take too much BONIVA, call your doctor. Do not try to vomit. Do not lie down.

What are the possible side effects of BONIVA?

BONIVA may cause serious side effects.

- See **“What is the most important information I should know about BONIVA?”**

The most common side effects of BONIVA are:

- Back pain
- Heartburn
- Stomach area (abdominal) pain
- Pain in your arms and legs
- Diarrhea
- Headache
- Muscle pain

Reference ID: 2895714

- Flu-like symptoms

You may get allergic reactions, such as hives or, in rare cases, swelling of your face, lips, tongue or throat.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of BONIVA. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How do I store BONIVA?

- Store BONIVA at room temperature, 59°F to 86°F (15°C to 30°C).
- Keep BONIVA in a tightly closed container.

Keep BONIVA and all medicines out of the reach of children.

General information about the safe and effective use of BONIVA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use BONIVA for a condition for which it was not prescribed. Do not give BONIVA to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about BONIVA. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about BONIVA that is written for health professionals.

For more information, go to www.myboniva.com or call 1-888-692-6648.

What are the ingredients in BONIVA?

Active ingredient: ibandronate sodium

Inactive ingredients: lactose monohydrate, povidone, microcrystalline cellulose, crospovidone, purified stearic acid, colloidal silicon dioxide, and purified water. Tablet film coating contains: hypromellose, titanium dioxide, talc, polyethylene glycol 6000 and purified water.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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