

MEDICATION GUIDE
Ibandronate Sodium Tablets
(eye-BAN-droe-nate SOE-dee-um)

Read the Medication Guide that comes with ibandronate sodium tablets 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 ibandronate sodium tablets.

What is the most important information I should know about ibandronate sodium tablets?

Ibandronate sodium tablets may 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 ibandronate sodium tablets 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 ibandronate sodium tablets exactly as prescribed to help lower your chance of getting esophagus problems (see the section “How should I take ibandronate sodium tablets?”).**
- **Stop taking ibandronate sodium tablets 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).

Ibandronate sodium tablets may lower the calcium levels in your blood. If you have low blood calcium before you start taking ibandronate sodium tablets, it may get worse during treatment. Your low blood calcium must be treated before you take ibandronate sodium tablets. 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 ibandronate sodium tablets. Take calcium and vitamin D as your doctor tells you to.

3. Bone, joint, or muscle pain.

Some people who take ibandronate sodium tablets develop severe bone, joint, or muscle pain.

4. Severe jaw bone problems (osteonecrosis).

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

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 are ibandronate sodium tablets?

Ibandronate sodium tablets are a prescription medicine used to treat or prevent osteoporosis in women after menopause. Ibandronate sodium tablets help increase bone mass and help reduce the chance of having a spinal fracture (break).

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

It is not known if ibandronate sodium tablets are safe and effective in children.

Who should not take ibandronate sodium tablets?

Do not take ibandronate sodium tablets 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 ibandronate sodium or any of its ingredients. A list of ingredients is at the end of this leaflet.

What should I tell my doctor before taking ibandronate sodium tablets?

Before you start ibandronate sodium tablets, 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)
- Are pregnant, or plan to become pregnant. It is not known if ibandronate sodium tablets can harm your unborn baby.
- Are breast-feeding or plan to breast-feed. It is not known if ibandronate sodium 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 ibandronate sodium tablets 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 ibandronate sodium tablets?

- Take ibandronate sodium tablets exactly as your doctor tells you.
- Take 1 ibandronate sodium tablet 150 mg 1 time every month on the same day each month.
- **Ibandronate sodium tablets works only if taken on an empty stomach.**
- Take 1 ibandronate sodium tablet, **after** you get up for the day and **before** taking your first food, drink, or other medicine.
- Take ibandronate sodium tablets while you are sitting or standing.
- **Do not chew or suck on a tablet of ibandronate sodium.**
- Swallow ibandronate sodium tablet with a full glass (6-8 oz) of plain water only.
- Do **not** take ibandronate sodium tablets with mineral water, coffee, tea, soda, or juice.

After swallowing ibandronate sodium 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 ibandronate sodium tablet and do not eat your first food of the day for at least 60 minutes after you take ibandronate sodium tablet.

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

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

What are the possible side effects of ibandronate sodium tablets?

Ibandronate sodium tablets may cause serious side effects.

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

The most common side effects of ibandronate sodium tablets are:

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

You may get allergic reactions, such as hives, breathing difficulties, swelling of your face, lips, tongue or throat, or feeling faint.

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 ibandronate sodium tablets. 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.

You may also report side effect to Macleods Pharma USA, Inc. at 1-888-943-3210

How do I store ibandronate sodium tablets?

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

Keep ibandronate sodium tablets and all medicines out of the reach of children.

General information about the safe and effective use of ibandronate sodium tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ibandronate sodium tablets for a condition for which it was not prescribed. Do not give ibandronate sodium tablets 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 ibandronate sodium tablets. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about ibandronate sodium tablets that is written for health professionals.

What are the ingredients in ibandronate sodium tablets?

Active ingredient: ibandronate sodium

Inactive ingredients: lactose monohydrate, povidone, microcrystalline cellulose, crospovidone, magnesium stearate, and colloidal silicon dioxide. The tablet film coating contains hypromellose, titanium dioxide, talc, and polyethylene glycol.

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

MACLEODS



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