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Ibandronate

pronounced as (i ban' droh nate)

Why is this medication prescribed?

Ibandronate is used to prevent and treat osteoporosis (a condition in which the bones become thin and weak and break easily) in women who have undergone menopause ("change of life," end of menstrual periods). Ibandronate is in a class of medications called bisphosphonates. It works by preventing bone breakdown and increasing bone density (thickness).

How should this medicine be used?

Ibandronate comes as a tablet to take by mouth. The 2.5-mg tablet is usually taken once a day in the morning on an empty stomach and the 150-mg tablet is usually taken once a month in the morning on an empty stomach. The 150-mg tablet should be taken on the same date each month. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take ibandronate exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Ibandronate may not work properly and may damage the esophagus (tube between the mouth and stomach) or cause sores in the mouth if it is not taken according to the following instructions. Tell your doctor if you do not understand, you do not think you will remember, or you are unable to follow these instructions:

- You must take ibandronate just after you get out of bed in the morning, before you eat or drink anything. Never take ibandronate at bedtime or before you wake up and get out of bed for the day.
- Swallow the tablets with a full glass (6 to 8 ounces [180 to 240 mL]) of plain water. Never take ibandronate with tea, coffee, juice, milk, mineral water, sparkling water, or any liquid other than plain water.
- Swallow the tablets whole; do not split, chew, or crush them. Do not suck on the tablets.
- After you take ibandronate, do not eat, drink, or take any other medications (including vitamins or antacids) for at least 60 minutes. Do not lie down for at least 60 minutes after you take ibandronate. Sit upright or stand upright for at least 60 minutes.

Ibandronate controls osteoporosis but does not cure it. Ibandronate helps to treat and prevent osteoporosis only as long as it is taken regularly. Continue to take ibandronate even if you feel well. Do not stop taking ibandronate without talking to your doctor, but talk to your doctor from time to time about whether you still need to take ibandronate.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with ibandronate and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>) or the manufacturer's website to obtain the Medication Guide.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking ibandronate,

- tell your doctor and pharmacist if you are allergic to ibandronate, any other medications, or any of the ingredients in ibandronate tablets. Ask your pharmacist for a list of the ingredients.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: angiogenesis inhibitors such as bevacizumab (Avastin), everolimus (Afinitor, Zortress), pazopanib (Votrient), sorafenib (Nexavar), or sunitinib (Sutent); aspirin and other nonsteroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen (Advil, Ibu-Tab, Motrin, others) and naproxen (Aleve, Naprelan, Naprosyn, others); cancer chemotherapy; and oral steroids such as dexamethasone, methylprednisolone (Medrol), and prednisone (Rayos). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- if you are taking any oral medications, including supplements, vitamins, or antacids, take them at least 60 minutes after you take ibandronate.
- tell your doctor if you are unable to sit upright or stand upright for at least 60 minutes and if you have or have ever had a low level of calcium in your blood. Your doctor may tell you not to take ibandronate.
- tell your doctor if you are undergoing radiation therapy and if you have or have ever had anemia (condition in which the red blood cells do not bring enough oxygen to all the parts of the body); difficulty swallowing; heartburn; ulcers or other problems with your stomach or esophagus (tube that connects the throat to the stomach); cancer; any type of infection, especially in your mouth; problems with your mouth, teeth, or gums; any condition that stops your blood from clotting normally; or kidney disease.
- tell your doctor if you are pregnant, plan to become pregnant, or are breastfeeding. Also tell your doctor if you plan to become pregnant at any time in the future, because ibandronate may remain in your body for years after you stop taking it. Call your doctor if you become pregnant during or after your treatment.
- you should know that ibandronate may cause osteonecrosis of the jaw (ONJ, a serious condition of the jaw bone), especially if you have dental surgery or treatment while you are taking the medication. A dentist should examine your teeth and perform any needed treatments, including cleaning or fixing ill-fitted dentures, before you start to take ibandronate. Be sure to brush your teeth and clean your mouth properly while you are taking ibandronate. Talk to your doctor before having any dental treatments while you are taking this medication.
- you should know that ibandronate may cause severe bone, muscle, or joint pain. You may begin to feel this pain within days, months, or years after you first take ibandronate. Although this type of pain may begin after you have taken ibandronate for some time, it is important for you and your doctor to

realize that it may be caused by ibandronate. Call your doctor right away if you experience severe pain at any time during your treatment with ibandronate. Your doctor may tell you to stop taking ibandronate and your pain may go away after you stop taking the medication.

- talk to your doctor about other things you can do to prevent osteoporosis from developing or worsening. Your doctor will probably tell you to avoid smoking and drinking large amounts of alcohol and to follow a regular program of weight-bearing exercise.

What special dietary instructions should I follow?

You should eat and drink plenty of foods and drinks that are rich in calcium and vitamin D while you are taking ibandronate. Your doctor will tell you which foods and drinks are good sources of these nutrients and how many servings you need each day. If you find it difficult to eat enough of these foods, tell your doctor. In that case, your doctor may prescribe or recommend a supplement.

What should I do if I forget a dose?

If you forget to take the daily 2.5-mg tablet, do not take it later in the day. Skip the missed dose and continue your regular dosing schedule the next morning. Do not take two tablets of ibandronate on the same day.

If you forget to take the once-monthly 150-mg tablet, and your next scheduled day to take ibandronate is more than 7 days away, take one tablet the morning after you remember. Then return to taking one tablet each month on the regularly scheduled date. If you forget to take the once-monthly 150-mg tablet and your next scheduled day to take ibandronate is 7 or fewer days away, skip the dose and wait for your next scheduled day. You should not take two 150-mg tablets of ibandronate within 1 week.

If you are not sure what to do if you miss a dose of ibandronate, call your doctor.

What side effects can this medication cause?

Ibandronate may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- nausea
- stomach pain
- diarrhea
- constipation
- weakness
- dizziness
- headache
- fever, sore throat, chills, cough, and other signs of infection
- frequent or urgent need to urinate
- painful urination

Some side effects can be serious. If you experience any of the following symptoms, call your doctor immediately before you take any more ibandronate:

- new or worsening heartburn
- difficulty swallowing
- pain on swallowing
- upper chest pain
- rash
- painful or swollen gums
- loosening of the teeth
- numbness or heavy feeling in the jaw
- poor healing of the jaw
- dull, aching pain in the hips, groin, or thighs

Ibandronate may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

Taking a bisphosphonate medication such as ibandronate for osteoporosis may increase the risk that you will break your thigh bone(s). You may feel pain in your hips, groin, or thighs for several weeks or months before the bone(s) break, and you may find that one or both of your thigh bones have broken even though you have not fallen or experienced other trauma. It is unusual for the thigh bone to break in healthy people, but people who have osteoporosis may break this bone even if they do not take ibandronate. Talk to your doctor about the risks of taking ibandronate.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps

and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

In case of emergency/overdose

In case of overdose, give the victim a full glass of milk and call your local poison control center at 1-800-222-1222. If the victim has collapsed or is not breathing, call local emergency services at 911. Do not allow the victim to lie down and do not try to make the victim vomit.

Symptoms of overdose may include the following:

- nausea
- stomach pain
- heartburn

What other information should I know?

Keep all appointments with your doctor. Your doctor may order certain tests to check your body's response to ibandronate.

Before having any bone imaging study, tell your doctor and healthcare personnel that you are taking ibandronate.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Boniva[®]

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