


 Roche

Patient Information

BONIVA[®] [bon-EE-va] (ibandronate sodium)

INJECTION

R_xonly

Read this patient information carefully before you receive BONIVA Injection. Read this patient information each time you get a refill for BONIVA Injection. There may be new information. This information does not take the place of talking with your health care provider about your condition or your treatment. Talk about BONIVA Injection with your health care provider before the first injection and at your regular check-ups.

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

BONIVA Injection must be administered intravenously only by a health care professional. **Do NOT administer BONIVA Injection to yourself.**

Patients with severe kidney problems should not receive BONIVA Injection.

Low blood calcium levels must be corrected before starting BONIVA Injection therapy. You also must take calcium and vitamin D supplements while receiving BONIVA Injection therapy.

What is BONIVA Injection?

BONIVA Injection is a prescription medicine used to treat osteoporosis in women after menopause (see the end of this leaflet for “**What is osteoporosis?**”).

BONIVA Injection may reverse bone loss by stopping more loss of bone and increasing bone mass in most women who receive the injection, even though they won't be able to see or feel a difference. BONIVA Injection may help lower the chances of breaking bones (fractures). These effects continue as long as you receive BONIVA Injection.

It is important that you receive your BONIVA Injection every 3 months for as long as your health care provider prescribes it. BONIVA Injection can treat your osteoporosis only if you continue to receive treatment.

Who should not receive BONIVA Injection?

Do not begin treatment with BONIVA Injection if you:

- have low blood calcium (hypocalcemia) or low blood vitamin D (hypovitaminosis D)
- have kidneys that work very poorly
- are allergic to ibandronate sodium or any of the other ingredients of BONIVA Injection (see the end of this leaflet for a list of all the ingredients in BONIVA Injection)

Tell your health care provider before using BONIVA Injection:

- if you are pregnant or planning to become pregnant. It is not known if BONIVA Injection can harm your unborn baby.
- if you are breast-feeding. It is not known if BONIVA Injection passes into your milk and if it can harm your baby.
- if you have kidney problems or other diseases that may affect your kidneys, such as diabetes, high blood pressure, or heart disease.
- if you are planning a dental procedure such as tooth extraction.

Tell your health care provider (including your dentist) about all the medicines you take, including prescription and non-prescription medicines, vitamins and supplements.

What is my BONIVA Injection schedule?

BONIVA Injection must be administered intravenously only by a health care professional. BONIVA Injection should be administered once every 3 months. If the dose is missed, you should contact your health care provider to schedule the next injection and to continue your treatment with BONIVA Injection. After receiving your missed dose, your next injection should be scheduled 3 months from the date of the last injection. If you are not sure what to do if you miss a dose, contact your health care provider who will be able to advise you.

What are the possible side effects of BONIVA Injection?

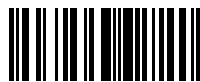
BONIVA Injection is generally well tolerated. Side effects with BONIVA Injection are usually mild and of brief duration.



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Common side effects with BONIVA Injection are:

- bone, muscle, or joint pains
- influenza-like illness
- headache

You may experience flu-like symptoms consisting of fever, chills, joint, bone and/or muscle pain, and fatigue. These symptoms usually occur only after the first injection and generally will not happen again as you continue treatment. Your health care provider or pharmacist can recommend a mild pain reliever such as aspirin to make you more comfortable. Without treatment, the symptoms generally disappear within 24 to 48 hours.

You may experience irritation at the site of injection, such as redness or swelling, but this does not happen often.

Rarely, patients have reported severe bone, joint, and/or muscle pain starting within one day to several months after beginning to take bisphosphonate drugs to treat osteoporosis (thin bones). This group of drugs includes BONIVA. Most patients experienced relief after stopping the drug. Contact your health care provider if you develop these symptoms after starting BONIVA.

Rarely, patients taking bisphosphonates have reported serious jaw problems associated with delayed healing and infection, often following dental procedures such as tooth extraction. If you experience jaw problems, please contact your health care provider and dentist.

These are not all the possible side effects of BONIVA Injection. For more information, ask your health care provider or pharmacist.

What is osteoporosis?

Osteoporosis is a disease that causes bones to become thinner. Thin bones can break easily. Most people think of their bones as being solid like a rock. Actually, bone is living tissue, just like other parts of the body, such as your heart, brain, or skin. Bone just happens to be a harder type of tissue. Bone is always changing. Your body keeps your bones strong and healthy by replacing old bone with new bone.

Osteoporosis causes the body to remove more bone than it replaces. This means that bones get weaker. Weak bones are more likely to break. Osteoporosis is a bone disease that is quite common in women after menopause. At first, osteoporosis has no symptoms, but people with osteoporosis may develop loss of height and are more likely to break (fracture) their bones, especially the back (spine), wrist, and hip bones. Eventually, the spine becomes curved and the body becomes bent over.

Osteoporosis can be prevented, and with proper therapy it can be treated.

Who is at risk for osteoporosis?

Talk to your health care provider about your chances for getting osteoporosis.

Many things put people at risk for osteoporosis. The following people have a higher chance of getting osteoporosis:

Women who:

- are going through or who are past menopause (“the change”)
- are white (Caucasian) or Asian

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People who:

- are thin
- have a family member with osteoporosis
- do not get enough calcium or vitamin D
- do not exercise
- smoke
- drink alcohol often
- take bone thinning medicines (like prednisone) for a long time

General information about BONIVA Injection

Medicines are sometimes prescribed for conditions that are not mentioned in patient information. Do not use BONIVA Injection for a condition for which it was not prescribed.

Store BONIVA Injection at 77°F (25°C) or at room temperature between 59° and 86°F (15° and 30°C).

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

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

For more information about BONIVA Injection, call 1-888-MY-BONIVA or visit www.myboniva.com.

What are the ingredients of BONIVA Injection?

BONIVA Injection (active ingredient): ibandronate sodium

BONIVA Injection (inactive ingredients): sodium chloride, glacial acetic acid, sodium acetate and water

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