MEDICATION GUIDE

Boniva® (bon-EE-va)
(ibandronate sodium)
Injection

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 treatment. Talk to your doctor if you have any questions about BONIVA.

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

BONIVA Injection is given in your vein (intravenously) and only given by a healthcare provider. Do not give BONIVA Injection to yourself.

BONIVA can cause serious side effects including:

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

1. 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.

2. Severe kidney problems.

Severe kidney problems, including kidney failure, may happen when you take BONIVA. Your doctor should perform blood tests to check your kidneys before you receive each treatment.

3. 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.

1

4. **Bone, joint, or muscle pain.**

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

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 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 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 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 low blood calcium
- Plan to have dental surgery or teeth removed
- Have kidney problems or other problems that may affect your kidneys
- 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 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.

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.

2

How will I receive BONIVA?

- BONIVA Injection is given 1 time every 3 months by a healthcare provider.
- If you miss a dose of BONIVA, call your doctor or healthcare provider to schedule your next dose.

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:

- Pain in your bones, joints or muscles
- Flu-like symptoms (fever, chills, bone, joint, or muscle pain, fatigue)
- Headache

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 should I handle BONIVA if I need to pick it up from a pharmacy?

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

- Keep BONIVA Injection 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: sodium chloride, glacial acetic acid, sodium acetate and water

3

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

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