**DESCRIPTION**

BONIVA® (ibandronate) is a solution for injection that inhibits selected osteoclastic bone resorption, thereby reducing bone turnover in postmenopausal women and men with osteoporosis.

**PHARMACOKINETICS**

Ibandronate is rapidly distributed throughout the body after injection. About 40% of the dose is removed from the circulation via bone absorption.

**CLINICAL PHARMACOLOGY**

*Absorption and Distribution*

BONIVA® (ibandronate) is rapidly distributed throughout the body after injection. About 40% of the dose is removed from the circulation via bone absorption.

**_*INDICATIONS AND USAGE_***

BONIVA® (ibandronate) Injection is indicated for the treatment of postmenopausal osteoporosis in women who have completed menopause and who are at high risk for fracture.

**_*CONTRAINDICATIONS_***

BONIVA® (ibandronate) Injection is contraindicated in patients who are hypersensitive to any component of this product.

**_*WARNINGS_***

Hypocalcemia: See WARNINGS: Hypocalcemia. The calcium levels of patients treated with BONIVA® should be monitored periodically. Symptoms of hypocalcemia may include nausea, vomiting, weakness, tetany, and other neuromuscular symptoms.

**_*PRECAUTIONS_***

**_*Geriatric Use_***

BONIVA® (ibandronate) Injection has not been studied in patients aged 80 years or older.

**_*REPRODUCTIVE TOXICITY_***

Pregnancy: In pregnant rats given intravenous doses of 0.05, 0.15, or 0.5 mg/kg/day from Day 17 post-coitum until Day 21 of gestation or from Day 5 post-coitum until Day 21 of gestation, maternal toxicity (drug-related maternal mortality or reduced maternal body weight), reduced litter size due to increased resorption rate, and/or reduced body weight at birth were observed at doses ≥0.1 mg/kg/day.

**_*DRUG INTERACTIONS_***

BONIVA® (ibandronate) Injection is not metabolized by CYP enzymes and is not an inhibitor of CYP enzymes.

**_*ADVERSE REACTIONS_***

Adverse reactions reported with BONIVA® Injection are generally mild to moderate.

**_*PHARMACOLOGICAL CATEGORY_***

BONIVA® (ibandronate) Injection is a solution for injection that inhibits selected osteoclastic bone resorption, thereby reducing bone turnover in postmenopausal women and men with osteoporosis.

**_*DOSE AND ADMINISTRATION_***

BONIVA® (ibandronate) Injection is administered as a single intravenous injection of 3 mg/3 mL (single-use, clear glass prefilled syringe) in patients who are at least 1 year past their last menstrual period. BONIVA® is administered as a single intravenous dose of 3 mg/3 mL (single-use, clear glass prefilled syringe) at least 3 months after the last oral dose of ibandronate. BONIVA® Injection should be administered weekly, every 3 weeks, or every 3 months, depending on the patient’s preference.

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VENIPUNCTURE

PRECAUTION: Keep hands behind the needle at all times during use and disposal. Observe Universal Precautions on ALL patients.

Aseptic technique, proper skin preparation and continued protection of the site are essential. Set up a sterile setup and ensure correct needle length and gauge. Use sterile gloves and ensure the needle is oriented correctly.

Open the package.

Remove tape, if present, from wings.

Secure the position of the winged infusion set per facility protocol.

Alternate (two-handed) method:

While keeping both hands behind the needle, grasp one of the wing tabs with your free hand. Line up the wings so that the shield is facing you with the needle pointing up. Carefully bring the needle to the puncture site. The needle will penetrate the skin and enter the vessel. The needle will be locked in place and ready for medication to flow through it. The safety shield will be in place and the needle will be securely held in place. A click will audible when the needle is locked in place. If the click does not happen, the needle may be incorrectly positioned. Continue to hold the needle in place and observe to ensure proper positioning in the vessel.

Recommended (one-handed) method: (Reference OSHA 1910.1030 (d)(2)(vii)(B))

While keeping both hands behind the needle, grasp one of the wing tabs with your free hand. Line up the wings so that the shield is facing you with the needle pointing up. Carefully bring the needle to the puncture site. The needle will penetrate the skin and enter the vessel. The needle will be locked in place and ready for medication to flow through it. The safety shield will be in place and the needle will be securely held in place. A click will audible when the needle is locked in place. If the click does not happen, the needle may be incorrectly positioned. Continue to hold the needle in place and observe to ensure proper positioning in the vessel.

Completely remove the needle from the puncture site and apply digital pressure to the site to control bleeding. Flip the safety shield forward toward needle. Grasp the wing and shield between your fingers and pull the needle out of the vessel. Remove the shield and discard it in the proper receptacle. Place the needle into the sharps container. Dispose of used needles and materials following the policies and procedures of your facility.