IBANDRONATE SODIUM injection, for intravenous use

IBANDRONATE SODIUM injection is not recommended for use in women with postmenopausal osteoporosis who have not been treated with bisphosphonates.

The percentage of patients who withdrew from treatment due to adverse reactions was 16% (ibandronate sodium injection) and 11% (placebo). The overall incidence of adverse reactions in the placebo and ibandronate sodium injection groups was 50% (ibandronate sodium injection) and 48% (placebo).

The following adverse reactions have been identified during post-approval use of ibandronate sodium injection:

-**Musculoskeletal Pain**: Abdominal pain, groin pain, extremity pain, back pain, vertebral fracture, leg pain, calf pain, vertebral body fracture.
-**Renal Impairment**: Acute renal failure, hypocalcemia, hypomagnesemia.
-**Rash**: Rash.
-**Hypocalcemia**: Hypocalcemia.
-**Anaphylactic Reaction**: Anaphylactic reaction.
-**Cystitis**: Cystitis.
-**Hypomagnesemia**: Hypomagnesemia.
-**Hypocalcemia**: Hypocalcemia.
-**Vertigo**: Vertigo.
-**Diarrhea**: Diarrhea.
-**Hypophosphatemia**: Hypophosphatemia.
-**Hypomagnesemia**: Hypomagnesemia.
-**Hypocalcemia**: Hypocalcemia.
-**Hypoglycemia**: Hypoglycemia.
-**Musculoskeletal Pain**: Musculoskeletal pain.
-**Hypomagnesemia**: Hypomagnesemia.
-**Fever**: Fever.
-**Gastrointestinal Disorders**: Gastrointestinal disorders.
-**Other**: Other.

Cases of anaphylaxis, including fatal events, have been reported with the use of ibandronate sodium injection. Cases have occurred predominantly in patients with a history of previous exposure to ibandronate sodium injection. Anaphylaxis can occur as early as minutes after the start of the infusion, but has been reported as late as 24 hours following dosing.

**WARNINGS AND PRECAUTIONS**

- Do not administer ibandronate sodium injection by any other route of administration.
- Stopping the bisphosphonate. A subset of patients had recurrence of symptoms several months after starting the drug. Most patients had relief of symptoms after stopping the bisphosphonate.
- A combination of abdominal pain and abdominal pain upper may occur, consider discontinuing use of the drug.
- May occur, consider discontinuing use of the drug.
- Treatment of Postmenopausal Osteoporosis
- The optimal duration of treatment of postmenopausal osteoporosis in postmenopausal women is based on clinical data of one year duration. The optimal duration of treatment of postmenopausal osteoporosis in postmenopausal women is not established. A continued reduction in the fracture risk of vertebrae was associated with the use of ibandronate sodium injection for 3 years to 10 years after the initial initiation of treatment.
- The clinical relevance of this data is not established.
- In postmenopausal women, it reduces the risk of vertebral fracture by 50% (ibandronate sodium injection) at 3 years and 62% (ibandronate sodium injection) at 5 years. In postmenopausal women, it reduces the risk of non-vertebral fractures by 40% (ibandronate sodium injection) at 3 years and 47% (ibandronate sodium injection) at 5 years.

**DOSAGE FORMS AND STRENGTHS**

- IBANDRONATE SODIUM injection, for intravenous use
- IBANDRONATE SODIUM monohydrate in 3 mL of solution, equivalent to a dose of 3 mg ibandronate free acid.

**RECOMMENDATIONS**

- Do not administer ibandronate sodium injection by any other route of administration.
- Stopping the bisphosphonate. A subset of patients had recurrence of symptoms several months after starting the drug. Most patients had relief of symptoms after stopping the bisphosphonate.
- Consider discontinuing use of the drug.
- The clinical relevance of this data is not established.
- In postmenopausal women, it reduces the risk of vertebral fracture by 50% (ibandronate sodium injection) at 3 years and 62% (ibandronate sodium injection) at 5 years. In postmenopausal women, it reduces the risk of non-vertebral fractures by 40% (ibandronate sodium injection) at 3 years and 47% (ibandronate sodium injection) at 5 years.

**ADVERSE REACTIONS**

- The most frequently reported adverse reactions were musculoskeletal pain, nausea, vomiting, and constipation.
- Other adverse reactions reported in a placebo-controlled clinical trial included infections and infestations, skin and appendages disorders, and gastrointestinal disorders.
- Cases of anaphylaxis, including fatal events, have been reported with the use of ibandronate sodium injection. Cases have occurred predominantly in patients with a history of previous exposure to ibandronate sodium injection. Anaphylaxis can occur as early as minutes after the start of the infusion, but has been reported as late as 24 hours following dosing.

**PHARMACOKINETICS**

- The absorption of ibandronate sodium injection is not significantly affected by food.
- Ibandronate sodium injection is eliminated by renal excretion. Based on in vitro studies, ibandronate sodium injection does not inhibit the cytochrome P450 system.
- The clearance of ibandronate sodium injection is proportional to creatinine clearance, indicating that dosage adjustment in renal impairment is not necessary.
- The drug's elimination is primarily by renal excretion. Based on in vitro studies, ibandronate sodium injection does not inhibit the cytochrome P450 system.

**NONCLINICAL TOXICOLOGY**

- No cases of overdose were reported in premarketing studies with ibandronate sodium injection.
- Periparturient mortality has also been observed with other bisphosphonates and appears to be a class effect related to inhibition of skeletal growth and development.

**REFERENCES**


**NOTICE**

- Ibandronate sodium injection is a nitrogen-containing bisphosphonate drug that inhibits osteoclast-mediated bone resorption and turnover. In postmenopausal women, it reduces the risk of vertebral fracture by 50% (ibandronate sodium injection) at 3 years and 62% (ibandronate sodium injection) at 5 years. In postmenopausal women, it reduces the risk of non-vertebral fractures by 40% (ibandronate sodium injection) at 3 years and 47% (ibandronate sodium injection) at 5 years.

**ADDITIONAL INFORMATION**

- Ibandronate sodium injection is not recommended for use in women with postmenopausal osteoporosis who have not been treated with bisphosphonates.
- The percentage of patients who withdrew from treatment due to adverse reactions was 16% (ibandronate sodium injection) and 11% (placebo).
- The overall incidence of adverse reactions in the placebo and ibandronate sodium injection groups was 50% (ibandronate sodium injection) and 48% (placebo).
- Cases of anaphylaxis, including fatal events, have been reported with the use of ibandronate sodium injection. Cases have occurred predominantly in patients with a history of previous exposure to ibandronate sodium injection. Anaphylaxis can occur as early as minutes after the start of the infusion, but has been reported as late as 24 hours following dosing.
- Ibandronate sodium injection is eliminated by renal excretion. Based on in vitro studies, ibandronate sodium injection does not inhibit the cytochrome P450 system.
IBANDRONATE may cause serious side effects.

Tell your doctor immediately if you have any of these side effects, or if you notice other side effects that are not listed.

1. Severe kidney problems (nephropathy)

2. Severe jaw bone problems (osteonecrosis)

3. Osteoporosis

4. Severe unexpected fractures in the thigh bone

5. Sperm production problems

6. Severe swelling in the joints

7. Enlarged prostate

8. Severe heart problems

9. Severe blood clots

10. Certain types of cancer

11. Severe or continuously increased tiredness

12. Infections

13. Skin problems

14. Vision or eye problems

15. Severe bleeding problems

16. Severe bone problems

17. Severe stomach problems

18. Severe tongue problems

19. Other serious side effects

Some people have developed unusual fractures in their thigh bone. Symptoms may include:

- Pain in the thigh that may be sharp or aching
- Difficulty walking, putting weight on the leg, or getting up from a chair
- Change in the way the leg moves or looks

Inform patients that the most common side effects of ibandronate sodium include:

- Fatigue
- Muscle pain
- Headache
- Joint pain
- Nausea
- Constipation
- Diarrhea
- Indigestion
- Vomiting

Inform patients Ibandronate Sodium Injection should not be administered to patients with known or suspected active osteoblastic tumors. Patients with active non-bone tumors may be at risk for increased tumor growth. Tumors can grow faster when bones are broken.

It is not known if IBANDRONATE is safe and effective in children.

Tell your doctor:

- If you are breastfeeding.
- If you are pregnant or plan to become pregnant. You should not take IBANDRONATE if you are pregnant. It is not known if IBANDRONATE will harm your unborn baby.
- If you have any skin allergies or other allergies.
- About all the medicines you take. This includes prescription and nonprescription medicines, vitamins, and herbal supplements.

You should see your doctor regularly to determine if IBANDRONATE is still right for you.

It is not known if IBANDRONATE will affect your ability to drive or operate machinery.

Medication Guide: IBANDRONATE

IBANDRONATE sodium injection is used to treat osteoporosis in postmenopausal women.

Before you receive IBANDRONATE, tell your doctor:

- About all your medical conditions.
- About all the medicines you take. This includes prescription and nonprescription medicines, vitamins, and herbal supplements.
- About all your allergies.

Caution:

- This Medication Guide summarizes the most important information about IBANDRONATE. It does not include all the information about IBANDRONATE.

More Information:

- See the end of this leaflet for a complete list of ingredients in IBANDRONATE.
- Ask your doctor or pharmacist for information about IBANDRONATE that is written for consumers.

Report adverse effects to the FDA at 1-800-FDA-1088. You may also report side effects to Sagent Pharmaceuticals, 333 Kennedy Blvd, Suite 400, West Nyack, NY 10994, 1-800-862-4898, or Fax 1-800-733-2952.