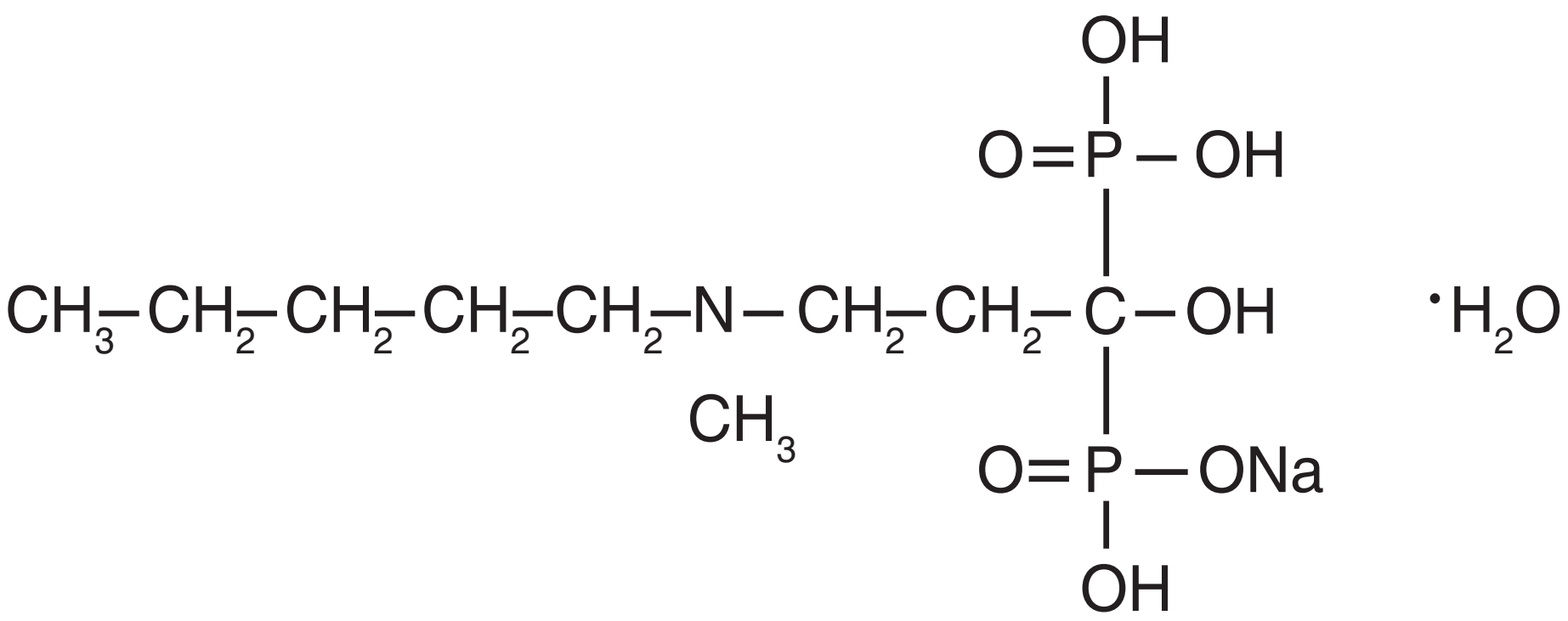
Ibnate®
(Ibandronic Acid)
Injection

3mg / 3ml
SOLUTION FOR
I.V. INJECTION

آئبنیٹ ۳ ملی گرام/۳ ملی لیٹر
(آئی بینڈرونیک ایسڈ)
انجکشن
صرف وریدی استعمال کے لئے

DESCRIPTION:

IBNATE (Ibandronate sodium) is a nitrogen-containing bisphosphonate that inhibits osteoclast-mediated bone resorption. The chemical name for ibandronate sodium is 3-(N-methyl-N-pentyl)amino-1-hydroxypropane-1,1diphosphonic acid, monosodium salt, monohydrate with the molecular formula $C_9H_{22}NO_7P_2Na\ H_2O$ and a molecular weight of 359.24.



IBNATE Injection is intended for intravenous administration only. IBNATE Injection is available as a sterile, clear, colourless, ready-to-use solution that delivers 3.375 mg of ibandronate monosodium salt monohydrate.

COMPOSITION:

Each 3ml contains: Ibandronate sodium eq. to Ibandronic acid....3mg
Genix Specs.

CLINICAL PHARMACOLOGY:

Mechanism of Action:

Ibandronate inhibits osteoclast activity and reduces bone resorption and turnover. In postmenopausal women, it reduces the elevated rate of bone turnover, leading to, on average, a net gain in bone mass.

PHARMACOKINETICS:

Distribution:

Area under the serum ibandronate concentrations versus time curve increases in a dose proportional manner after administration of 2 mg to 6 mg by intravenous injection.

After administration, ibandronate either rapidly binds to bone or is excreted into urine. In humans, the apparent terminal volume of distribution is at least 90 L, and the amount of dose removed from the circulation into the bone is estimated to be 40% to 50% of the circulating dose. In one study, in vitro protein binding in human serum was approximately 86% over an ibandronate concentration range of 20 to 2000 ng/Ml.

Metabolism

There is no evidence that ibandronate is metabolized in humans. Ibandronate does not inhibit human P450 1A2, 2A6, 2C9, 2C19, 2D6, 2E1, and 3A4 isozymes in vitro. Ibandronate does not undergo hepatic metabolism and does not inhibit the hepatic cytochrome P450 system.

Elimination

The portion of ibandronate that is not removed from the circulation via bone absorption is eliminated unchanged by the kidney (approximately 50% to 60% of the administered

intravenous dose).
Cmax within 3 or 8 hours after intravenous or oral administration, respectively. The observed apparent terminal half-life for intravenous 2 and 4 mg ibandronate after 2 hours of infusion ranges from 4.6 to 15.3 hours and 5 to 25.5 hours, respectively.
Following intravenous administration, total clearance of ibandronate is low, with average values in the range 84 to 160 mL/min.

INDICATIONS:

IBNATE Injection is indicated for the treatment of osteoporosis in postmenopausal women. In postmenopausal women with osteoporosis, IBNATE increases bone mineral density (BMD) and reduces the incidence of vertebral fractures

Pharmacokinetics in Specific Populations:
Pediatrics:
The pharmacokinetics of ibandronate have not been studied in patients less than 18 years of age.

Geriatric:
Since ibandronate is not known to be metabolized, the only difference in ibandronate elimination for geriatric patients versus younger patients is expected to relate to progressive age-related changes in renal function

Hepatic Impairment:
No studies have been performed to assess the pharmacokinetics of ibandronate in patients with hepatic impairment since ibandronate is not metabolized in the human liver.

DRUG INTERACTION:

Melphalan/Prednisolone:
Ibandronate did not interact with melphalan or prednisolone.

Tamoxifen A:
pharmacokinetic interaction study in healthy postmenopausal women demonstrated that there was no interaction between oral 30 mg tamoxifen and intravenous 2 mg ibandronate.

DOSAGE AND ADMINISTRATION:

Important Administration Instructions:
IBNATE Injection must be administered intravenously only by a health care professional. Care must be taken not to administer intra-arterially or paravenously as this could lead to tissue damag Appropriate medical support and monitoring measures should be readily available when IBNATE Injection is administered. If anaphylactic or other severe hypersensitivity/allergic reactions occur, immediately discontinue the injection and initiate appropriate treatment Discard any unused portion. Do not mix with calcium-containing solutions or other intravenously administered drugs.

Dosage Information:
The recommended dose of IBNATE Injection for the treatment of postmenopausal osteoporosis is 3 mg every 3 months administered intravenously over a period of 15 to 30 seconds. Do not administer more frequently than once every 3 months.

Dosing After Missed Dose:
If the dose is missed, administer as soon as it can be re-scheduled. Thereafter, IBNATE Injection should be scheduled every 3 months from the date of the last injection.

Dosage Modifications In Patients With Renal Impairment:
Do not administer to patients with severe renal impairment (creatinine clearance less

than 30 mL/minute) No dose adjustment is necessary for patients with mild or moderate renal impairment (creatinine clearance greater than or equal to 30 mL/min)

SIDE EFFECTS:

1. Hypocalcemia and Mineral Metabolism
2. Anaphylactic Reaction
3. Renal Impairment
4. Tissue Damage Related to Inappropriate

Drug Administration

5. Osteonecrosis of the Jaw
6. Musculoskeletal Pain Atypical
7. Subtrochanteric and Diaphyseal Femoral Fractures

OVERDOSE:

No cases of overdose were reported in premarketing studies with IBNATE Injection.

CONTRAINDICATIONS:

IBNATE is contraindicated in patients with the following conditions:

1. Hypocalcemia
2. Known hypersensitivity to IBNATE Injection or to any of its excipients. Cases of anaphylaxis, including fatal events, have been reported.

Pregnacy:

There are no adequate and well-controlled studies in pregnant women. IBNATE Injection should be used during pregnancy only if the potential benefit justifies the potential risk to the mother and fetus.

DOSAGE:

One injection once in three months or as directed by the physician.

INSTRUCTIONS:

Store below 30°C. Protect from heat & light.
Keep all medicines out of the reach of children.

WARNING:
To be sold on the prescription of a registered medical practitioner only.

PRESENTATION:

Ibnate (Ibandronic Acid) for Injection is available in pack of 1 Vial.

خوراک: ایک انجکشن ۳ مہینے میں ایک دفعہ یا ڈاکٹر کی ہدایات کے مطابق استعمال کریں۔
ہدایات: ۳۰ ڈگری سینٹی گریڈ سے کم پر رکھیں۔
روشنی اور گرمی سے محفوظ رکھیں۔
تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔
محلول دھندلا ہو یا اس میں کوئی شے نظر آئے تو ہرگز استعمال نہ کریں۔
انتباہ: صرف رجسٹرڈ ڈاکٹر کے نسخہ پر فروخت کریں۔

For detailed information:

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