FONDRONIC 4 mg/5 mL

Concentrate for Solution for Infusion

Zoledronic acid monohydrate

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2. Qualitative and Quantitative Composition

- **Active Substance:**
  Each 5ml contains Zoledronic acid monohydrate equivalent to Zoledronic acid **4mg**

For the full list of excipients, see section 6.1.

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3. Pharmaceutical Form
Solution for infusion.

- Description: Clear and colorless solution.

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4. Clinical Particulars

4.1 Therapeutic Indications
FONDRONIC is indicated for the treatment of:

- **Hypercalcemia of Malignancy (HCM):**
  In patients with serum calcium corrected for albumin (cCa) ≥12 mg/dL (3.0 mmol/L).
- **Bone Metastases and Multiple Myeloma:**
  As part of standard antineoplastic therapy in adult patients with:
  - Multiple myeloma.
  - Documented bone metastases from solid tumors (e.g., breast, prostate cancer).
    - In prostate cancer, patients should have progressed after at least one hormonal therapy.

4.2 Posology and Method of Administration
Treatment should be initiated and supervised by a healthcare professional experienced in managing cancer and related conditions.

- **Hypercalcemia of Malignancy:**
  - 4 mg as a single-use intravenous infusion over at least **15 minutes**.
  - Retreatment can be given after a minimum of **7 days** if serum calcium levels remain elevated.
- **Bone Metastases/Multiple Myeloma:**
  - **4 mg** every 3–4 weeks, as a single-use intravenous infusion over at least **15 minutes**.
  - Patients should also receive **500 mg calcium** and **400 IU vitamin D** orally daily.

Special Populations

- **Hepatic Impairment:** No dose adjustment required, but caution is advised in severe hepatic impairment due to limited data.
- **Renal Impairment:**
    - Baseline renal function determines dosage:
        - CrCl >60 mL/min: **4 mg**.
        - CrCl 50–60 mL/min: **3.5 mg**.
        - CrCl 40–49 mL/min: **3.3 mg**.
        - CrCl 30–39 mL/min: **3.0 mg**.
        - CrCl <30 mL/min: Contraindicated.
    - Measure serum creatinine before each dose.
- **Paediatric Population:** Not recommended.

Method of Administration

- Administer as an **intravenous infusion over at least 15 minutes**.
- Do not mix with calcium-containing solutions.
- Administer using a separate line.

4.3 Contraindications

- Hypersensitivity to zoledronic acid or any excipients.
- Severe renal impairment (CrCl <30 mL/min).
- Combination with Ra-223 due to increased risks of fractures and mortality.

4.4 Special Warnings and Precautions for Use

- **Renal Impairment:** Risk of renal failure. Monitor serum creatinine before each dose.
- **Osteonecrosis of the Jaw (ONJ):**
    - Patients should undergo a dental exam and avoid invasive dental procedures.
- **Hypocalcemia:**
    - Correct before starting therapy. Supplement calcium and vitamin D.
- **Atypical Femoral Fractures:** Monitor for thigh, hip, or groin pain.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

- **Nephrotoxic Drugs:** Use with caution.

- **Aminoglycosides/Calcitonin:** Additive hypocalcemic effect.
- **Loop Diuretics:** May increase risk of hypocalcemia.

4.6 Fertility, Pregnancy, and Lactation

- **Pregnancy:** Contraindicated.
- **Contraception in Males:** Use effective contraception during treatment and for one week after the last dose.
- **Breastfeeding:** Contraindicated.
- **Fertility:** Zoledronic acid may affect male fertility.

4.7 Effects on Ability to Drive and Use Machines

FONDRONIC has no or negligible influence on the ability to drive or operate machinery.

4.8 Undesirable Effects

- **Very Common (≥1/10):** Nausea, fatigue, anemia, bone pain, hypophosphatemia, fever.
- **Common (≥1/100 to <1/10):** Hypertension, hypocalcemia, osteonecrosis of the jaw.
- **Uncommon (≥1/1,000 to <1/100):** Renal dysfunction, muscle spasms.

4.9 Overdose

- Symptoms: Hypocalcemia, hypophosphatemia, hypomagnesemia.
- Management: Supportive therapy with calcium gluconate, phosphate, or magnesium sulfate.

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5. Pharmacological Properties

5.1 Pharmacodynamic Properties

- **Pharmacotherapeutic Group:** Bisphosphonates, ATC code: M05BA08.
- **Mechanism of Action:** Inhibits osteoclast-mediated bone resorption.

5.2 Pharmacokinetic Properties

- **Absorption:** Rapidly distributed after IV administration.
- **Elimination:** Primarily excreted via the kidneys.

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6. Pharmaceutical Particulars

6.1 List of Excipients

- Mannitol
- Sodium citrate
- Water for injection

6.3 Shelf Life

[Specify shelf life, e.g., 3 years.]

6.4 Special Precautions for Storage

- Store at **25°C**.

6.5 Nature and Contents of Container

- Packaged in **single-use 5 mL vials**.

6.6 Special Precautions for Disposal

- Women who are pregnant should not handle FONDRONIC without protection.
- Dispose of unused medicine according to local regulations.

Manufacturer:

Imported & marketed by:

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