Kemidat 6 mg/6 ml vial, containing concentrated solution for IV infusion

COMPOSITION: Each vial contains 6.75 mg ibandronic acid, monosodium salt and monohydrate equivalent to 6 mg ibandronic acid in concentrated solution for 6 ml infusion.

PHARMACOLOGICAL PROPERTIES: Ibandronic acid is a very potent biphosphonate of the nitrogen-containing group of bisphosphonates that is effective on bone tissue and that specifically inhibits the osteoclast effect. Ibandronic acid decreases bone resorption without showing a direct effect on bone development. It decreases bone resorption by selectively inhibiting osteoclast activity and thus decreases skeletal complications associated with malignancies.

INDICATIONS: Kemidat is indicated in prevention of skeletal events in breast-cancer patients with bone metastasis (radiotherapy and surgery-requiring complications and pathological fractures) and treatment of hypercalcemia of tumor-origin of metastatic or non-metastatic disease.

CONTRAINDICATIONS: Kemidat is contraindicated in hypocalcemia. Kemidat is also contraindicated in patients hypersensitive to ibandronic acid or any of the other ingredients of the pharmaceutical preparation. Precautions should be taken in patients known to be hypersensitive to other bisphosphonates. Kemidat should not be used in children.

WARNINGS AND PRECAUTIONS: No dosage adjustment is required in patients with renal/hepatic failure, mild renal failure. In placebo-controlled randomized studies conducted in patients with bone metastasis due to breast cancer, no evidence of deterioration in renal function was observed during prolonged ibandronic acid treatment. However, depending on each patient’s clinical evaluation, it is recommended that renal function, serum calcium, phosphate and magnesium levels should be monitored in patients given ibandronic acid therapy. Since there is no clinical data, no dosage recommendation is available for patients with severe hepatic failure. Excessive hydration should be avoided in patients at risk for heart failure. In cases where daily intake is insufficient, patients should be given calcium and vitamin D support. In cancer patients who receive various treatment regimes including IV bisphosphonates, cases of tooth extraction and/or jaw osteonecrosis associated with local infection (including osteomyelitis) have been reported; therefore, a dental control with an appropriate protective dental care should be considered prior to bisphosphonate therapy. Pregnancy category: C

SIDE EFFECTS / ADVERSE EFFECTS: Hypocalcemia, bone pain, fever. Serum calcium level can fall to hypocalcemic values. Diarrhea, dyspepsia, nausea, gastrointestinal pain, teeth irregularities, astenia, dizziness, parathyroid irregularities, sense of thirst, influenzae-like disease, peripheral edema.

DRUG INTERACTIONS: Kemidat should not be mixed with calcium-containing solutions. Ibandronic acid is eliminated by renal secretion only and does not undergo biotransformation. Secretion pathways do not seem to include the known acidic or basic transport systems that play a role in excretion of other active materials. Furthermore, ibandronic acid does not inhibit major human hepatic P450 isoenzymes. Since both drugs decrease serum calcium levels for long periods of time, precaution should be taken when bisphosphonates are co-administered with aminoglycosides. In addition, presence of hypomagnesemia should be monitored.
DOSAGE AND ADMINISTRATION: The recommended dosage for prevention of skeletal problems in breast cancer patients with bone metastasis is 6 mg intravenous infusion given every 3-4 weeks. This dosage should be given by infusion over at least 15 minutes. For infusion, the contents of the vial should be added to isotonic sodium chloride solution or 5% dextrose solution. The shorter infusion period (for example; 15 minutes) should be used only for patients with normal renal function or for patients with mild renal failure. There is no data for defining a short infusion period for patients with creatinine clearance <50 ml/min. In treatment of hypercalcemia developing due to tumor, the patient should initially be rehydrated sufficiently with 0.9% sodium chloride. In most of the patients with severe hypercalcemia, a single 4 mg dose is sufficient. Kemidat should be administered by intravenous infusion. The infusion solution containing the product is chemically and physically stable for 24 hours (keep at room temperature at <25°C). Unless dilution is performed under controlled and validated aseptic conditions, the duration until use should not be over 24 hours at 2-8°C.

STORAGE CONDITIONS: Keep at room temperature <25°C. The product should be used immediately after reconstitution; the product that will not be used immediately should be kept in the refrigerator (2-8°C) for a maximum of 24 hours.

AVAILABLE FORMS: Kemidat 6 mg/6ml vial containing concentrated solution for IV infusion, in 1 vial packages. Sold under prescription. Please consult our company for detailed information.

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