**DENIVUS® KABI**

**54794 GRevised May 2014**

**DENAZAMOX® SODIUM PHOSPHATE INJECTION, USP**

**DESCRIPTION:**

Denaizamox sodium phosphate is a water-soluble, monovalent salt of denazamox sodium, a 1,4-benzodiazepine derivative. It is chemically known as 4-[[1,4-benzodiazepine-4,7(1H,5H)-dione 5,11-(dihydrogen phosphate)]-methyl]phenyl]acetamide. The empirical formula is C<sub>26</sub>H<sub>25</sub>N<sub>3</sub>O<sub>9</sub>Na and the molecular weight is 589.43.

**INDICATIONS AND USAGE:**

The use of denazamox sodium phosphate injection is contraindicated in patients who are hypersensitive to denazamox sodium, sodium phosphate, or any other constituent of this medication.

**CONTRAINDICATIONS:**

Do not inject denazamox sodium phosphate into an infected site which may be subject to contamination. Intramuscularly administered denazamox sodium phosphate may be painful. This product should be used with caution in patients with a history of hypercalcemia or hyperparathyroidism.

**WARNINGS:**

Hypercalcemia or hyperparathyroidism unresponsive to conventional therapy. The use of denazamox sodium phosphate may be associated with the following adverse reactions:

- Hypercalcemia
- Hypercalcemic crisis
- Hyperphosphatemia
- Hyperkalemia
- Hypernatremia
- Hypokalemia
- Hypomagnesemia
- Hypocalcemia
- Hypoglycemia
- Hypothyroidism
- Hypothyroid crisis
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intrasynovial therapy around the face and head
Subcutaneous or intramuscular therapy
Sterile doses
Parenteral drug products should be inspected... whenever the solution and container are unaltered.

OVERDOSAGE:
Reports of acute toxicity and/or death following overdosage of dexamethasone are rare in the event of overdosage, no specific antidote is available; treatment is supportive and symptomatic.

The oral LD50 of dexamethasone sodium phosphate in female mice was 4 mg/kg.

Acute Allergic Disorder
In acute, welldifferentiated allergic disorders or acute exacerbations of chronic allergic disorders, the following dosage schedule containing prednisone acetate... is useful in the management of patients with recurrent or inoperable tumors; chemotherapy of leukemia with two or more agents, and organ transplantation.

DOSAGE AND ADMINISTRATION:
Dexamethasone sodium phosphate injection, 4 mg/mL. For intravenous, intramuscular, intra-articular, intratendinous, and soft tissue injection.

The initial dosage should be as great as can be safely administered, and the maintenance dosage should be the lowest dosage that maintains an adequate clinical response. While in severe diseases doses lower than 0.5 mg may suffice when the disease condition is grave or irreversible, the usual adult dosage is 0.5 to 4 mg daily in divided doses, and severe cases require higher doses. Doses of 12 to 20 mg daily may be required in certain overwhelming, acute, or exacerbations of the disease, individual drug changes in clinical status resulting from remissions or exacerbations may require dosage adjustments, including the risk of overdosage in chronic cases.

Intravenous and Intramuscular Injections: The initial dosage of dexamethasone sodium phosphate injection varies from 0.5 to 1 mg a day for the control of perioperative anxiety, and severe disease doses lower than 0.5 mg may suffice, while in severe diseases doses higher than 8 mg may be required. For the initial dose should be that which will maintain a satisfactory clinical response. If a satisfactory clinical response is obtained, the proper maintenance dosage should be determined by decreasing the initial dosage in small amounts to the lowest dosage that maintains an adequate clinical response. Patients should be observed closely for signs that may require dosage adjustment, including changes in clinical status resulting from remissions or exacerbations of the disease, and the patient’s response to therapy during acute episodes, while minimizing the risk of overdosage in chronic cases.

Acute Allergic Disorders: Dexamethasone sodium phosphate injection is particularly recommended for use in conjunction with one of the less sedating, longer-acting antihistamines for intramuscular and soft tissue injection.


REFERENCES: