**Injection of a steroid into an infected site is** to conventional treatment of infections:

- **Sulfite sensitivity**: Sodium bisulfite, a sulfite that may cause an anaphylactic reaction, is present in sulfite-sensitive individuals.
- **Sodium content**: Dexamethasone sodium phosphate contains sodium, which may be important in patients on a sodium-restricted diet.

**CLINICAL PHARMACOLOGY:**

- **Dexamethasone sodium phosphate** has a rapid onset of action and is useful in cases where a drug is needed for immediate effect. It is commonly used in the treatment of the adrenal insufficiency caused by ovariectomy in the horse.
- **Available forms**: In clinical situations where the treatment of adrenal insufficiency caused by ovariectomy in the horse requires the use of a drug that is effective in the acute phase of adrenal insufficiency, dexamethasone sodium phosphate is the drug of choice.
- **Adverse effects**: Major adverse drug reactions include hypoinsulinemia and hyperglycemia. Hypokalemia, hypocalcemia, and hypomagnesemia can also occur. Minor adverse drug reactions include gastrointestinal upset, skin reactions, and fluid retention.
- **Drug interactions**: Dexamethasone may alter the course or interpretation of certain diagnostic tests. Potentially harmful drug interactions can occur. The concurrent use of corticosteroids and other drugs (including antibiotics, anticoagulants, anti-inflammatories, antifungals, antihistamines, antiplatelet agents, calcium channel blockers, diuretics, immunomodulators, and cyclic nucleotide phosphodiesterase inhibitors) can lead to cumulative side effects.

**CONTRAINDICATIONS:**

- **Allergic reactions** have been reported for dexamethasone sodium phosphate. These reactions have been reported in patients with a known history of allergy to corticosteroids.
- **Pregnancy**: Dexamethasone sodium phosphate should be used with caution during pregnancy. It is not known whether the drug crosses the placenta or affects the fetus. However, it is recommended that women who are pregnant or planning to become pregnant consult their healthcare provider before using dexamethasone sodium phosphate.
- **Lactation**: Dexamethasone sodium phosphate is excreted in breast milk. It is unknown whether it may cause adverse effects in the infant. Mothers should not breastfeed while using the drug.

**WARNINGS:**

- **Hypokalemia**: Potassium depletion can occur with the use of dexamethasone sodium phosphate. This can lead to hypokalemia, which is characterized by muscle weakness, flaccid paralysis, and cardiac arrhythmias.

**PRECAUTIONS:**

- **Multiple sclerosis**: Dexamethasone sodium phosphate may cause increased intracranial pressure in patients with multiple sclerosis.

**ADVERSE REACTIONS:**

- **General**:
  - **Hypokalemia**: Potassium depletion can occur with the use of dexamethasone sodium phosphate. This can lead to hypokalemia, which is characterized by muscle weakness, flaccid paralysis, and cardiac arrhythmias.
  - **Increased intracranial pressure**: Dexamethasone sodium phosphate may cause increased intracranial pressure in patients with multiple sclerosis.

- **Local**:
  - **Ocular**: Cataracts, increased intraocular pressure, glaucoma, and secondary glaucoma can occur with the use of dexamethasone sodium phosphate.

**DRUG INTERACTIONS:**

- **Corticosteroids and other drugs**: Potentially harmful drug interactions can occur. The concurrent use of corticosteroids and other drugs (including antibiotics, anticoagulants, anti-inflammatories, antifungals, antihistamines, antiplatelet agents, calcium channel blockers, diuretics, immunomodulators, and cyclic nucleotide phosphodiesterase inhibitors) can lead to cumulative side effects.

**TERATOGENIC EFFECTS**: Pregnancy Category C—

**REPRODUCTION STUDIES:**

- **Dexamethasone sodium phosphate** has not been shown to affect fertility in the rat or rabbit. However, there have been reports of reduced fertility in animals treated with dexamethasone sodium phosphate. Therefore, it is recommended that women who are pregnant or planning to become pregnant consult their healthcare provider before using dexamethasone sodium phosphate.

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Acute Allergic Disorders

In acute, self-limited allergic disorders or acute exacerbations of chronic allergic disorders, the following dosage schedule combining parenteral and oral therapy may be employed:

**Parenteral Therapy during acute episodes, while minimizing oral therapy during remissions**

Dexamethasone sodium phosphate injection, 4 mg/kg, single intravenous injection, every 4 to 6 hours while shock persists, to provide a single intravenous injection dose of approximately 4 mg per kg body weight. After shock subsides, intravenous injection every 2 to 6 hours while shock persists.

**Oral Therapy**

Large Joints

- Fourth day, 2 tablets in two divided doses
- Fifth and sixth days, 1 tablet each day
- Seventh day, no treatment

Small Joints

- Fourth day, two divided doses
- Fifth, sixth, and seventh days, no treatment

Temporomandibular (TMJ) Joint

- Fourth and fifth days, 4 tablets in two divided doses
- Sixth day, 2 tablets in two divided doses
- Seventh day, no treatment

Soft Tissue Infiltration

- Single intra-articular injection may result in damage to joint tissues.

Some of the usual single dose are

**Site of Injection**

<table>
<thead>
<tr>
<th>Site of Injection</th>
<th>Amount of Dexamethasone Sodium Phosphate (mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large Joints</td>
<td>2 to 4</td>
</tr>
<tr>
<td>Small Joints</td>
<td></td>
</tr>
<tr>
<td>Tendon Sheath</td>
<td>0 to 2</td>
</tr>
<tr>
<td>Soft Tissue Infiltration</td>
<td>0 to 2</td>
</tr>
</tbody>
</table>

**REFERENCES:**


11,17-dihydroxy-16-methyl-21-(phosphonooxy)...

Flow diagrams are not included as they are not available in the provided text format.
Patients should be observed closely for signs that might require dosage adjustment, including changes in clinical status resulting from remis- sion or exacerbation of underlying disease, drug responsiveness, and the effect of stress (e.g., surgery, infection, trauma). During stress it may be necessary to increase dosage temporarily. The drug is to be stopped after more than six months of use. If treatment is to be resumed, it should be withdrawn gradually.

When the intravenous route of administration is used, dosage usually should be the same as the oral dosage. In cancer, overwhelming, acute, or chronic infections, or in disease states associated with severe stress, the dosage of corticosteroids may have to be increased temporarily. The slow rate of absorption by intramuscular administration should be recognized.

**Shock**

Any of the previously mentioned indications for high-potency agents may be potentiated by the use of high-dose, intravenous corticosteroid therapy in the treatment of shock. Unfortunately, corticosteroid therapy is not effective in the treatment of anaphylactic shock. The following dosages of dexamethasone sodium phosphate injection have been suggested by various authors:

**Author** Dosage

Cavanagh1 3 mg/kg of body weight per 24 hours to a constant intravenous infusion during the first 24 hours and then 2 mg/kg of body weight every 6 hours while shock persists.

Frank2 40 mg initially followed by repeated single intravenous doses of 2 mg/kg of body weight every 6 hours while shock persists.

Dake3 40 mg initially followed by repeated single intravenous doses of 2 mg/kg of body weight every 6 hours while shock persists.

Schorner4 40 mg initially followed by repeated single intravenous doses of 2 mg/kg of body weight every 6 hours while shock persists.

Administration of high-dose corticosteroid therapy should be continued until the patient’s condition has stabilized and usually not longer than 48 to 72 hours. Although adverse reactions associated with high-dose, short-term corticosteroid therapy are uncommon, peptic ulceration may occur.

**Cerebral Edema**

Dexamethasone sodium phosphate injection is generally administered initially in a dosage of 10 mg intravenously every 4 to 6 hours intravenously until the symptoms of cerebral edema subside. Response is usually noted within 2 to 4 hours and dosage may be reduced after ten to four days and gradually discontinued over a period of five to seven days. The maintenance dosage usually should be the same as the initial oral dosage. In certain overwhelming, acute, or chronic infections or exacerbations of disease, individual adjustment of the dosage is recommended. Maintenance therapy with 2 mg two or three times a day may be effective.

**Acute Allergic Disorders**

In acute, self-limited allergic disorders or acute exacerbations of chronic allergic diseases, the following schedules of corticosteroid doses have been used:

**Corticosteroid**

Dexamethasone sodium phosphate injection, USP (Preservative Free) equivalent to 10 mg dexamethasone per mL, is supplied in a single intravenous injection:

<table>
<thead>
<tr>
<th>Product</th>
<th>NDC</th>
<th>No.</th>
<th>Strength</th>
<th>Vial Size</th>
<th>Per mL</th>
<th>Per 10 mL</th>
<th>Per 100 mL</th>
<th>Per 1000 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>591450</td>
<td>50325-516-10</td>
<td>10 mg</td>
<td>10 mL</td>
<td>10 mg</td>
<td>100 mg</td>
<td>1,000 mg</td>
<td>10,000 mg</td>
<td></td>
</tr>
</tbody>
</table>

This container closure is not made with natural rubber latex.

**Storage**

Store at 20° to 25°C (68° to 77°F) [see USP Con- 

victional Temperature]. Sensitive to heat. Do not autoclave.

Protect from freezing.

**REFERENCES:**


500601 63323-506-01 10 mg 1 mL vial,

Fresenius Kabi USA, LLC

Lake Zurich, IL 60047

545655

5AV

Cross Tech–74239–Proof 1

Form M02Fresenius Kabi USA, LLC O. 4500139607–Job No. 45955E4/30/14–hc–Indd4

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