Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension, USP

DESCRIPTION

Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension, USP is a white to practically white, odorless powder, and is a suspension of commercially pure betamethasone sodium phosphate and betamethasone acetate 2 mg in 1 ml. The product contains the following inactive ingredients: phenol, metaphosphoric acid, and sodium hydroxide. Phenol is a preservative and metaphosphoric acid is an anticoagulant.

Each milliliter contains:
- Betamethasone sodium phosphate, 2 mg
- Betamethasone acetate, 2 mg

The suspension is isotonic with normal saline solution and buffered to a pH range of 5.4-6.4. Phenol, 0.1% (w/v), is a preservative.

INDICATIONS

Betamethasone sodium phosphate is indicated for the intralesional administration of corticosteroids for the management of localized inflammatory and pruritic dermatoses, including:
- cutaneous disorders, such as lichen planus, lichen simplex chronicus (neurodermatitis), and psoriatic plaques; necrobiosis lipoidica and lichen striatus; localized hypertrophic, infiltrated, inflammatory lesions of granuloma annulare, lichen planus, and lichen nitidus
- anaplastic lymphoma; intralesional treatment of keloids
- localized hypertrophic, inflammatory lesions of granuloma annulare, lichen planus, lichen nitidus, necrobiosis lipoidica, lichen striatus, and cutaneous reactions to foreign proteins
- localized hypertrophic, inflammatory lesions of keloids
- lichen nitidus

Betamethasone sodium phosphate is a corticosteroid that is indicated: for the diagnosis of sepsis is confirmed, appropriate antimicrobial therapy should be instituted. If this complication occurs and the diagnosis of sepsis is confirmed, appropriate antimicrobial therapy should be instituted. If the diagnosis of sepsis is confirmed, appropriate antimicrobial therapy should be instituted.

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Betamethasone Acetate Injectable Suspension is indicated in the management of disorders characterized by inflammation or edema in which a corticosteroid may be considered for therapy. Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension is indicated in the management of disorders characterized by inflammation or edema in which a corticosteroid may be considered for therapy.

**Dosage and Administration**

- **Local Anesthetic**: Using sterile technique, a 20- to 24-gauge needle is used to withdraw the medication from the vial. The local anesthetic is then drawn up in the syringe. If other local anesthetics are being used, the needles should be exchanged.
- **Intravenous Administration**: Do not use Betamethasone Acetate Injectable Suspension as a vein push. Betamethasone Acetate Injectable Suspension may be given as an intravenous bolus injection or by slow intravenous infusion. When given intravenously, Betamethasone Acetate Injectable Suspension should be administered through a flexible catheter and should be infused slowly. The rate of infusion should not exceed 10 mg per minute. Administration should be preceded by the intravenous injection of saline or dextrose solution compatible with the Betamethasone Acetate Injectable Suspension.
- **Infusion**:
  - Diluent: Sterile Water for Injection or Sodium Chloride Injection, 0.9%.
  - The recommended dilution is 0.1 to 0.5 mg/mL.
  - Administration:
    - For parenteral administration, the duration of intravenous infusions not exceeding 1 hour, the rate of infusion should not exceed 10 mg per minute. The rate of infusion should not exceed 60 mg per hour. The duration of intravenous infusions exceeding 1 hour, the rate of infusion should not exceed 40 mg per hour.

**WARNING**

- **Skin Tests**: Skin tests with corticosteroids have been reported to cause false-positive reactions in some patients. Betamethasone Acetate Injectable Suspension should not be used as a skin test. However, if skin tests with corticosteroids are used, Betamethasone Acetate Injectable Suspension may cause a rapid reaction with the development of local pruritus, erythema, and edema.

**Drug Interactions**

- **Nonsteroidal Anti-inflammatory Agents (NSAIDS)**: NSAIDS, especially aspirin, may decrease the hepatic metabolism of corticosteroids and thereby decrease corticosteroid half-life.
- **Estrogens**: Estrogens may decrease the hepatic metabolism of certain corticosteroids, thereby increasing their half-life.
- **Cyclosporine**: Cyclosporine decreases corticosteroid metabolism and may cause corticosteroid toxicity.
- **Cholestyramine**: Cholestyramine may decrease corticosteroid metabolism and may cause corticosteroid toxicity.
- **Macrolide Antibiotics**: Macrolide antibiotics have been reported to cause a significant decrease in corticosteroid metabolism and may cause corticosteroid toxicity.
- **Antibiotics**: Antibiotics may decrease corticosteroid metabolism and may cause corticosteroid toxicity.
- **Cimetidine**: Cimetidine decreases corticosteroid metabolism and may cause corticosteroid toxicity.
- **Protein binders**: Protein binders may decrease corticosteroid metabolism and may cause corticosteroid toxicity.

**CAUTIONS**

- **Hepatitis**: Patients with a history of hepatitis or who are suspected of having hepatitis should be monitored closely.
- **Adrenal Insufficiency**: Patients with adrenal insufficiency should be monitored closely.
- **Pregnancy**: Betamethasone Acetate Injectable Suspension is not recommended for in utero use.
- **Rhabdomyolysis**: Rhabdomyolysis has been reported with corticosteroids, including Betamethasone Acetate Injectable Suspension.
- **Increased Intravascular Volume**: Betamethasone Acetate Injectable Suspension may cause an increase in intravascular volume.
- **Withdrawal from Steroids**: Withdrawing corticosteroids, including Betamethasone Acetate Injectable Suspension, may cause adrenal insufficiency.

**CONTRAINDICATIONS**

- **Pregnancy**: Betamethasone Acetate Injectable Suspension is contraindicated in pregnancy.
- **Alcohol Intoxication**: Betamethasone Acetate Injectable Suspension is contraindicated in alcohol intoxication.
- **Hypersensitivity to Betamethasone Acetate Injectable Suspension**: Betamethasone Acetate Injectable Suspension is contraindicated in patients who have shown hypersensitivity to Betamethasone Acetate Injectable Suspension.
- **Known or Suspected Infection**: Betamethasone Acetate Injectable Suspension is contraindicated in patients with known or suspected infection.

**ADVERSE REACTIONS**

- **Hypertension**: Hypertension has been reported with Betamethasone Acetate Injectable Suspension.
- **Glucose Intolerance**: Glucose intolerance has been reported with Betamethasone Acetate Injectable Suspension.
- **Diabetes Mellitus**: Diabetes mellitus has been reported with Betamethasone Acetate Injectable Suspension.
- **Increased Blood Glucose**: Increased blood glucose levels have been reported with Betamethasone Acetate Injectable Suspension.
- **Skin Reactions**: Skin reactions have been reported with Betamethasone Acetate Injectable Suspension.

**OVERDOSAGE**

- **Symptoms**: Overdosage may cause CNS depression, convulsions, hypotension, and ataxia.
- **Treatment**: Treatment of corticosteroid overdose is primarily symptomatic and supportive. However, corticosteroids should be discontinued if overdosage occurs.

**NURSING CONSIDERATIONS**

- **Storage**: Betamethasone Acetate Injectable Suspension should be stored at room temperature and protected from light.
- **Laboratory Tests**: Laboratory tests should be performed to monitor the patient's response to therapy.

**PATIENT EDUCATION**

- **Skin Testing**: Skin testing with corticosteroids has been reported to cause false-positive reactions in some patients. Betamethasone Acetate Injectable Suspension should not be used as a skin test.
- **Drug Interactions**: Patients should be aware of the potential for drug interactions with corticosteroids, including Betamethasone Acetate Injectable Suspension.

**REFERENCES**

- **Clinical Studies**: Clinical studies have been reported with corticosteroids, including Betamethasone Acetate Injectable Suspension.
- **Literature Review**: Literature review has been reported with corticosteroids, including Betamethasone Acetate Injectable Suspension.

**PATIENT INFORMATION**

- **Side Effects**: Patients should be informed of the potential side effects of corticosteroids, including Betamethasone Acetate Injectable Suspension.
- **Precautions**: Patients should be advised to report any adverse reactions to their healthcare provider.

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