DOUBLEDEX KIT- dexamethasone sodium phosphate, povidine iodine
Asclemed USA, Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

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Dexamethasone Sodium Phosphate Injection, USP

For Intravenous or Intramuscular Use Only
Rx only

DESCRIPTION

Dexamethasone Sodium Phosphate Injection, USP, is a water-soluble inorganic ester of dexamethasone which produces a rapid response even when injected intramuscularly.

Dexamethasone Sodium Phosphate, USP chemically is Pregna-1,4-diene-3,20-dione, 9-fluoro-11,17-dihydroxy-16-methyl-21-(phosphonooxy)-, disodium salt, (11ß, 16α).

It occurs as a white to creamy white powder, is exceedingly hygroscopic, is soluble in water and its solutions have a pH between 7.0 and 8.5. It has the following structural formula:

\[
\text{CH}_2\text{OPO(ONa)}_2
\]

\[
\text{C}_{22}\text{H}_{26}\text{FNa}_2\text{O}_8\text{P}
\]

M.W. 516.41

Each mL of Dexamethasone Sodium Phosphate Injection, USP (Preservative Free) contains dexamethasone sodium phosphate, USP equivalent to 10 mg dexamethasone phosphate; 24.75 mg sodium citrate, dihydrate; and Water for Injection, q.s. pH adjusted with citric acid or sodium hydroxide, if necessary. pH: 7.0 to 8.5.

Each mL Dexamethasone Sodium Phosphate Injection, USP (Preserved) contains dexamethasone sodium phosphate, USP equivalent to 10 mg dexamethasone phosphate; 13.5 mg sodium citrate, dihydrate; 10 mg benzyl alcohol; and Water for Injection, q.s. pH adjusted with citric acid or sodium hydroxide, if necessary. pH: 7.0 to 8.5.

CLINICAL PHARMACOLOGY

Dexamethasone sodium phosphate injection has a rapid onset but short duration of action when compared with less soluble preparations. Because of this, it is suitable for the treatment of acute disorders responsive to adrenocortical steroid therapy.

Naturally occurring glucocorticoids (hydrocortisone and cortisone), which also have salt-retaining properties, are used as replacement therapy in adrenocortical deficiency states. Their synthetic analogs, including dexamethasone, are primarily used for their potent anti-inflammatory effects in disorders of many organ systems.
Glucocorticoids cause profound and varied metabolic effects. In addition, they modify the body’s immune responses to diverse stimuli.

At equipotent anti-inflammatory doses, dexamethasone almost completely lacks the sodium-retaining property of hydrocortisone and closely related derivatives of hydrocortisone.

**INDICATIONS AND USAGE**

**By intravenous or intramuscular injection when oral therapy is not feasible:**

1. **Endocrine Disorders**
   - Primary or secondary adrenocortical insufficiency (hydrocortisone or cortisone is the drug of choice; synthetic analogs may be used in conjunction with mineralocorticoids
     - where applicable; in infancy, mineralocorticoid supplementation is of particular importance).
   - Acute adrenocortical insufficiency (hydrocortisone or cortisone is the drug of choice; mineralocorticoid supplementation may be necessary, particularly when synthetic analogs are used).
   - Preoperatively, and in the event of serious trauma or illness, in patients with known adrenal insufficiency or when adrenocortical reserve is doubtful.
   - Shock unresponsive to conventional therapy if adrenocortical insufficiency exists or is suspected.
   - Congenital adrenal hyperplasia
   - Nonsuppurative thyroiditis
   - Hypercalcemia associated with cancer

2. **Rheumatic Disorders**
   - As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in:
     - Post-traumatic osteoarthritis
     - Synovitis of osteoarthritis
     - Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy).
     - Acute and subacute bursitis
     - Epicondylitis
     - Acute nonspecific tenosynovitis
     - Acute gouty arthritis
     - Psoriatic arthritis
     - Ankylosing spondylitis

3. **Collagen Diseases**
   - During an exacerbation or as maintenance therapy in selected cases of:
     - Systemic lupus erythematosus
     - Acute rheumatic carditis

4. **Dermatologic Diseases**
   - Pemphigus
Severe erythema multiforme (Stevens-Johnson syndrome)
Exfoliative dermatitis
Bullous dermatitis herpetiformis
Severe seborrheic dermatitis
Severe psoriasis
Mycosis fungoides

5. Allergic States
Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment in:
   Bronchial asthma
   Contact dermatitis
   Atopic dermatitis
   Serum sickness
   Seasonal or perennial allergic rhinitis
   Drug hypersensitivity reactions
   Urticarial transfusion reactions
   Acute noninfectious laryngeal edema (epinephrine is the drug of first choice).

6. Ophthalmic Diseases
Severe acute and chronic allergic and inflammatory processes involving the eye, such as:
   Herpes zoster ophthalmicus
   Iritis, iridocyclitis
   Chorioretinitis
   Diffuse posterior uveitis and choroiditis
   Optic neuritis
   Sympathetic ophthalmia
   Anterior segment inflammation
   Allergic conjunctivitis
   Keratitis
   Allergic corneal marginal ulcers

7. Gastrointestinal Diseases
To tide the patient over a critical period of the disease in:
   Ulcerative colitis (systemic therapy)
   Regional enteritis (systemic therapy)

8. Respiratory Diseases
Symptomatic sarcoidosis
Berylliosis
Fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate
antituberculous chemotherapy.

Loeffler’s syndrome not manageable by other means.
Aspiration pneumonitis

9. Hematologic Disorders
   Acquired (autoimmune) hemolytic anemia.
   Idiopathic thrombocytopenic purpura in adults
   (IV only; IM administration is contraindicated).
   Secondary thrombocytopenia in adults
   Erythroblastopenia (RBC anemia)
   Congenital (erythroid) hypoplastic anemia

10. Neoplastic Diseases
   For palliative management of:
   Leukemias and lymphomas in adults
   Acute leukemia of childhood

11. Edematous States
   To induce diuresis or remission of proteinuria in the nephrotic syndrome, without uremia, of the
   idiopathic type or that due to lupus erythematosus.

12. Miscellaneous
   Tuberculous meningitis with subarachnoid block or impending block when used concurrently with
   appropriate antituberculous chemotherapy.
   Trichinosis with neurologic or myocardial involvement.

13. Diagnostic testing of adrenocortical hyperfunction.

14. Cerebral Edema associated with primary or metastatic brain tumor, craniotomy, or head injury. Use
   in cerebral edema is not a substitute for careful neurosurgical evaluation
   and definitive management such as neurosurgery or other specific therapy.

CONTRAINDICATIONS
Systemic fungal infections (see WARNINGS regarding amphotericin B).
Hypersensitivity to any component of this product (see WARNINGS).

WARNINGS
Because rare instances of anaphylactoid reactions have occurred in patients receiving parenteral
corticosteroid therapy, appropriate precautionary measures should be taken prior to administration,
especially when the patient has a history of allergy to any drug. Anaphylactoid and hypersensitivity
reactions have been reported for dexamethasone sodium phosphate injection (see ADVERSE
REACTIONS).

Corticosteroids may exacerbate systemic fungal infections and, therefore, should not be used in the
presence of such infections unless they are needed to control drug reactions due to amphotericin B.
Moreover, there have been cases reported in which concomitant use of amphotericin B and
hydrocortisone was followed by cardiac enlargement and congestive failure.
In patients on corticosteroid therapy subjected to any unusual stress, increased dosage of rapidly acting corticosteroids before, during, and after the stressful situation is indicated.

Drug-induced secondary adrenocortical insufficiency may result from too rapid withdrawal of corticosteroids and may be minimized by gradual reduction of dosage. This type of relative insufficiency may persist for months after discontinuation of therapy; therefore, in any situation of stress occurring during that period, hormone therapy should be reinstituted. If the patient is receiving steroids already, dosage may have to be increased. Since mineralocorticoid secretion may be impaired, salt and/or a mineralocorticoid should be administered concurrently.

Corticosteroids may mask some signs of infection, and new infections may appear during their use. There may be decreased resistance and inability to localize infection when corticosteroids are used. Moreover, corticosteroids may affect the nitroblue-tetrazolium test for bacterial infection and produce false negative results.

In cerebral malaria, a double-blind trial has shown that the use of corticosteroids is associated with prolongation of coma and a higher incidence of pneumonia and gastrointestinal bleeding.

Corticosteroids may activate latent amebiasis. Therefore, it is recommended that latent or active amebiasis be ruled out before initiating corticosteroid therapy in any patient who has spent time in the tropics or in any patient with unexplained diarrhea.

Prolonged use of corticosteroids may produce posterior subcapsular cataracts, glaucoma with possible damage to the optic nerves, and may enhance the establishment of secondary ocular infections due to fungi or viruses.

Average and large doses of cortisol or hydrocortisone can cause elevation of blood pressure, salt and water retention, and increased excretion of potassium. These effects are less likely to occur with the synthetic derivatives except when used in large doses. Dietary salt restriction and potassium supplementation may be necessary. All corticosteroids increase calcium excretion.

Administration of live virus vaccines, including smallpox, is contraindicated in individuals receiving immunosuppressive doses of corticosteroids. If inactivated viral or bacterial vaccines are administered to individuals receiving immunosuppressive doses of corticosteroids, the expected serum antibody response may not be obtained. However, immunization procedures may be undertaken in patients who are receiving corticosteroids as replacement therapy, e.g., for Addison's disease.

Patients who are on drugs which suppress the immune system are more susceptible to infections than healthy individuals. Chickenpox and measles, for example, can have a more serious or even fatal course in non-immune children or adults on corticosteroids. In such children or adults who have not had these diseases, particular care should be taken to avoid exposure. The risk of developing a disseminated infection varies among individuals and can be related to the dose, route and duration of corticosteroid administration as well as to the underlying disease. If exposed to chickenpox, prophylaxis with varicella zoster immune globulin (VZIG) may be indicated. If chickenpox develops, treatment with antiviral agents may be considered. If exposed to measles, prophylaxis with immune globulin (IG) may be indicated. (See the respective package inserts for VZIG and IG for complete prescribing information).

The use of dexamethasone sodium phosphate injection in active tuberculosis should be restricted to those cases of fulminating or disseminated tuberculosis in which the corticosteroid is used for the management of the disease in conjunction with an appropriate antituberculous regimen.

If corticosteroids are indicated in patients with latent tuberculosis or tuberculin reactivity, close observation is necessary as reactivation of the disease may occur. During prolonged corticosteroid therapy, these patients should receive chemoprophylaxis.

Literature reports suggest an apparent association between use of corticosteroids and left ventricular free wall rupture after a recent myocardial infarction; therefore, therapy with corticosteroids should be used with great caution in these patients.
Usage in Pregnancy

Since adequate human reproduction studies have not been done with corticosteroids, use of these drugs in pregnancy or in women of childbearing potential requires that the anticipated benefits be weighed against the possible hazards to the mother and embryo or fetus. Infants born of mothers who have received substantial doses of corticosteroids during pregnancy should be carefully observed for signs of hypoadrenalism.

Corticosteroids appear in breast milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other unwanted effects. Mothers taking pharmacologic doses of corticosteroids should be advised not to nurse.

PRECAUTIONS

This product, like many other steroid formulations, is sensitive to heat. Therefore, it should not be autoclaved when it is desirable to sterilize the exterior of the vial.

Following prolonged therapy, withdrawal of corticosteroids may result in symptoms of the corticosteroid withdrawal syndrome including fever, myalgia, arthralgia, and malaise. This may occur in patients even without evidence of adrenal insufficiency.

There is an enhanced effect of corticosteroids in patients with hypothyroidism and in those with cirrhosis.

Corticosteroids should be used cautiously in patients with ocular herpes simplex for fear of corneal perforation.

The lowest possible dose of corticosteroid should be used to control the condition under treatment, and when reduction in dosage is possible, the reduction must be gradual.

Psychic derangements may appear when corticosteroids are used, ranging from euphoria, insomnia, mood swings, personality changes, and severe depression to frank psychotic manifestations. Also, existing emotional instability or psychotic tendencies may be aggravated by corticosteroids.

Aspirin should be used within caution in conjunction with corticosteroids in hypoprothrombinemia.

Steroids should be used with caution in nonspecific ulcerative colitis, if there is a probability of impending perforation, abscess, or other pyogenic infection, also in diverticulitis, fresh intestinal anastomoses, active or latent peptic ulcer, renal insufficiency, hypertension, osteoporosis, and myasthenia gravis. Signs of peritoneal irritation following gastrointestinal perforation in patients receiving large doses of corticosteroids may be minimal or absent. Fat embolism has been reported as a possible complication of hypercortisonism.

When large doses are given, some authorities advise that antacids be administered between meals to help prevent peptic ulcer.

Steroids may increase or decrease motility and number of spermatozoa in some patients.

Phenytoin, phenobarbital, ephedrine, and rifampin may enhance the metabolic clearance of corticosteroids resulting in decreased blood levels and lessened physiologic activity, thus requiring adjustment in corticosteroid dosage. These interactions may interfere with dexamethasone suppression tests which should be interpreted with caution during administration of these drugs.

False negative results in the dexamethasone suppression test (DST) in patients being treated with indomethacin have been reported. Thus, results of the DST should be interpreted with caution in these patients.

The prothrombin time should be checked frequently in patients who are receiving corticosteroids and coumarin anticoagulants at the same time because of reports that corticosteroids have altered the response to these anticoagulants. Studies have shown that the usual effect produced by adding
corticosteroids is inhibition of response to coumarins, although there have been some conflicting reports of potentiation not substantiated by studies.

When corticosteroids are administered concomitantly with potassium-depleting diuretics, patients should be observed closely for development of hypokalemia.

The slower rate of absorption by intramuscular administration should be recognized.

**Information for Patients**

Susceptible patients who are on immunosuppressant doses of corticosteroids should be warned to avoid exposure to chickenpox or measles. Patients should also be advised that if they are exposed, medical advice should be sought without delay.

**Pediatric Use**

Growth and development of infants and children patients on prolonged corticosteroid therapy should be carefully followed.

**ADVERSE REACTIONS**

Fluid and electrolyte disturbances:
- Sodium retention
- Fluid retention
- Congestive heart failure in susceptible patients
- Potassium loss
- Hypokalemic alkalosis
- Hypertension

Musculoskeletal:
- Muscle weakness
- Steroid myopathy
- Loss of muscle mass
- Osteoporosis
- Vertebral compression fractures
- Aseptic necrosis of femoral and humeral heads
- Tendon rupture
- Pathologic fracture of long bones

Gastrointestinal:
- Peptic ulcer with possible subsequent perforation and hemorrhage
- Perforation of the small and large bowel; particularly in patients with inflammatory bowel disease
- Pancreatitis
- Abdominal distention
- Ulcerative esophagitis

Dermatologic:
Impaired wound healing
Thin fragile skin
Petechiae and ecchymoses
Erythema
Increased sweating
May suppress reactions to skin tests
Burning or tingling, especially in the perineal area (after IV injection)
Other cutaneous reactions, such as allergic dermatitis, urticaria, angioneurotic edema

Neurologic:
Convulsions
Increased intracranial pressure with papilledema (pseudotumor cerebri) usually after treatment
Vertigo
Headache
Psychic disturbances

Endocrine:
Menstrual irregularities
Development of cushingoid state
Suppression of growth in pediatric patients
Secondary adrenocortical and pituitary unresponsiveness, particularly in times of stress, as in trauma, surgery, or illness
Decreased carbohydrate tolerance
Manifestations of latent diabetes mellitus
Increased requirements for insulin or oral hypoglycemic agents in diabetics
Hirsutism

Ophthalmic:
Posterior subcapsular cataracts
Increased intraocular pressure
Glaucoma
Exophthalmos
Retinopathy of prematurity

Metabolic:
Negative nitrogen balance due to protein catabolism

Cardiovascular:
Myocardial rupture following recent myocardial infarction (see WARNINGS)
Hypertrophic cardiomyopathy in low birth weight infants

Other:
Anaphylactoid or hypersensitivity reactions
Thromboembolism
Weight gain
Increased appetite
Nausea
Malaise
Hiccups

The following additional adverse reactions are related to parenteral corticosteroid therapy:

Hyperpigmentation or hypopigmentation
Subcutaneous and cutaneous atrophy
Sterile abscess
Charcot-like arthropathy

OVERDOSAGE

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

The oral LD\textsubscript{50} of dexamethasone in female mice was 6.5 g/kg. The intravenous LD\textsubscript{50} of dexamethasone sodium phosphate in female mice was 794 mg/kg.

DOSAGE AND ADMINISTRATION

Dexamethasone sodium phosphate injection, 10 mg/mL—For intravenous and intramuscular injection only.

Dexamethasone sodium phosphate injection can be given directly from the vial, or it can be added to Sodium Chloride Injection or Dextrose Injection and administered by intravenous drip.

Solutions used for intravenous administration or further dilution of this product should be preservative free when used in the neonate, especially the premature infant.

When it is mixed with an infusion solution, sterile precautions should be observed. Since infusion solutions generally do not contain preservatives, mixtures should be used within 24 hours.

DOSAGE REQUIREMENTS ARE VARIABLE AND MUST BE INDIVIDUALIZED ON THE BASIS OF THE DISEASE AND THE RESPONSE OF THE PATIENT.

Intravenous and Intramuscular Injection

The initial dosage of dexamethasone sodium phosphate injection varies from 0.5 to 9 mg a day depending on the disease being treated. In less severe diseases doses lower than 0.5 mg may suffice, while in severe diseases doses higher than 9 mg may be required.

The initial dosage should be maintained or adjusted until the patient’s response is satisfactory. If a satisfactory clinical response does not occur after a reasonable period of time, discontinue dexamethasone sodium phosphate injection and transfer the patient to other therapy.

After a favorable initial response, 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 might require dosage adjustment, including changes in clinical status resulting from remissions or exacerbations of the disease, individual drug responsiveness, and the effect of stress (e.g., surgery, infection, trauma). During stress it may be
necessary to increase dosage temporarily. If the drug is to be stopped after more than a few days of treatment, it usually should be withdrawn gradually.

When the intravenous route of administration is used, dosage usually should be the same as the oral dosage. In certain overwhelming, acute, life-threatening situations, however, administration in dosages exceeding the usual dosages may be justified and may be in multiples of the oral dosages. The slower rate of absorption by intramuscular administration should be recognized.

**Shock**

There is a tendency in current medical practice to use high (pharmacologic) doses of corticosteroids for the treatment of unresponsive shock. The following dosages of dexamethasone sodium phosphate injection have been suggested by various authors:

<table>
<thead>
<tr>
<th>Author</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cavanagh(^1)</td>
<td>3 mg/kg of body weight per 24 hours by constant intravenous infusion after an initial intravenous injection of 20 mg</td>
</tr>
<tr>
<td>Dietzman(^2)</td>
<td>2 to 6 mg/kg of body weight as a single intravenous injection</td>
</tr>
<tr>
<td>Frank(^3)</td>
<td>40 mg initially followed by repeat intravenous injection every 4 to 6 hours while shock persists</td>
</tr>
<tr>
<td>Oaks(^4)</td>
<td>40 mg initially followed by repeat intravenous injection every 2 to 6 hours while shock persists</td>
</tr>
<tr>
<td>Schumer(^5)</td>
<td>1 mg/kg of body weight as a single intravenous injection</td>
</tr>
</tbody>
</table>

Administration of high dose corticosteroid therapy should be continued only 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 followed by four mg every six hours intramuscularly until the symptoms of cerebral edema subside. Response is usually noted within 12 to 24 hours and dosage may be reduced after two to four days and gradually discontinued over a period of five to seven days. For palliative management of patients with recurrent or inoperable brain tumors, 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 disorders, the following dosage schedule combining parenteral and oral therapy is suggested:

Dexamethasone sodium phosphate injection, *first day*, 4 or 8 mg intramuscularly.

Dexamethasone tablets, 0.75 mg: *second and third days*, 4 tablets in two divided doses each day; *fourth day*, 2 tablets in two divided doses; *fifth and sixth days*, 1 tablet each day; *seventh day*, no treatment; *eighth day*, follow-up visit.

This schedule is designed to ensure adequate therapy during acute episodes, while minimizing the risk of overdosage in chronic cases.
Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever the solution and container permit.

**HOW SUPPLIED**

Dexamethasone Sodium Phosphate Injection, USP (Preservative Free) equivalent to 10 mg dexamethasone phosphate, is supplied in a single dose vial as follows:

<table>
<thead>
<tr>
<th>Product No.</th>
<th>NDC No.</th>
<th>Strength</th>
<th>Vial Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>500601</td>
<td>63323-506-01</td>
<td>10 mg/mL</td>
<td>1 mL</td>
</tr>
</tbody>
</table>

Packaged in twenty-fives.

Dexamethasone Sodium Phosphate Injection, USP (Preserved) equivalent to 10 mg dexamethasone phosphate, is supplied in a multiple dose vial as follows:

<table>
<thead>
<tr>
<th>Product No.</th>
<th>NDC No.</th>
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<th>Vial Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>501610</td>
<td>63323-516-10</td>
<td>10 mg/mL</td>
<td>10 mL</td>
</tr>
</tbody>
</table>

Packaged in tens.

Vial stoppers do not contain natural rubber latex.

**Storage**

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Sensitive to heat. Do not autoclave.

Protect from freezing.

Protect from light.

**Single dose vials**–Store in container until time of use. Discard unused portion.

**Multiple dose vials**–Store in container until contents are used.

**REFERENCES**

Active Ingredient | Purpose
---|---
Povidone Iodine 10% v/v | Antiseptic

**Purpose:**
- First aid antiseptic to help prevent skin infection in minor cuts, scrapes and burns.
- For preparation of the skin prior to surgery.
- Helps reduce bacteria that can potentially cause skin infections.

**Warnings:**

Section Text
- **FOR EXTERNAL USE ONLY**

**Do not use:**
- As a first aid antiseptic for more than 1 week.
- In the eyes.
- Over large areas of the body.

**Ask a doctor before use if you have:**
- Deep puncture wounds
- Animal bites
- Serious burns

**Stop Use:**
- If irritation and redness develop
- If condition persists for more than 72 hours, consult a physician.

**Keep Out Of Reach Of Children**

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center.

**Directions Povidone iodine:**

Tear at notch, remove applicator, use only once.

**As a first aid antiseptic**
- clean affected area
- apply 1 to 3 times daily
• may be covered with a sterile bandage, if bandaged let dry.

For preoperative patient skin preparation
• clean area
• apply to operative site prior to surgery using the applicator

Other information:
Store at room temperature.
Avoid excessive heat
For use as an
• first aid antiseptic
• pre-operative skin preparation

Inactive Ingredients
Inactive ingredients: nonoxynol-9, water

Active ingredient
Isopropyl Alcohol 70% v/v

Purpose
Antiseptic

Uses
For first aid to decrease germs in
• minor cuts
• scrapes
• burns

For preparation of the skin prior to injection

Warnings
For external use only
Flammable - keep away from fire or flame

Do not use
with electrocautery procedures

When using this product do not
• get into eyes
• apply over large areas of the body
• in case of deep or puncture wounds, animal bites or serious burns consult a doctor
Stop use and ask a doctor if
• condition persists or gets worse or lasts for more than 72 hours
• do not use longer than 1 week unless directed by a doctor

Keep out of reach of children.
If swallowed, get medical help or contact a Poison Control Center right away.

Directions
• apply to skin as needed
• discard after single use

Other information
Protect from freezing and avoid excessive heat

Inactive ingredient
Water

PACKAGE LABEL - PRINCIPAL DISPLAY - Dexamethasone 1 mL
NDC 63323-506-01
500601
DEXAMETHASONE SODIUM PHOSPHATE INJECTION, USP
10 mg/mL*
For IV or IM Use Only Rx only
1 mL Single Dose Vial
Preservative Free
Discard unused portion
PROTECT FROM LIGHT.
Swabsticks
dynarex®
Antiseptic/Germicide
For External Use Only
Made In Israel
Reorder No. 1202

Principal Display Panel –
CURAD®
STERILE
ALCOHOL
PREP PAD
MADE With 70% isopropyl alcohol
2-PLY
PAD
OFFERS EXCELLENT CLEANSING ACTION
For external use only.
Not labeled for individual sale.
Sterile in unopened, undamaged package.
1 MEDIUM
PREP
PAD
DoubleDex™

Kit Contains

2 Dexamethasone Sodium Phosphate Inj., USP 10mg/mL (1mL)
1 Povidone-Iodine Swabsticks (3 Swabs)
1 Gebauer's Pain Ease® (30mL)
1 BD Integra Syringe with Retracting BD PrecisionGlide™ Needle (3mL 23G x 1”
1 BD Integra Syringe with Retracting BD PrecisionGlide™ Needle (3mL 25G x 1”)
1 Pair Nitrile Powder Free Sterile Gloves (M)
1 Drape
1 Adhesive Bandage
3 Isopropyl Alcohol 70% Prep Pads
5 Non-sterile 4x4 gauze
1 Face mask
1 Dose
Single Use Only
Distributed by Enovachem™
PHARMACEUTICALS
Torrance, CA 90501

NDC: 76420-766-01

DoubleDex™

Kit Contains
  2 Dexamethasone Sodium Phosphate Inj., USP 10mg/mL (1mL)
  1 Povidone-Iodine Swabsticks (3 Swabs)
  1 Gebauer’s Pain Ease® (30mL)
  1 BD Integra Syringe with Retracting BD PrecisionGlide™ Needle (3mL 23G x 1”)
  1 BD Integra Syringe with Retracting BD PrecisionGlide™ Needle (3mL 25G x 1”)
  1 Pair Nitrile Powder Free Sterile Gloves (M)
  1 Drape
  1 Adhesive Bandage
  3 Isopropyl Alcohol 70% Prep Pad
  5 Non-sterile 4x4 gauze
  1 Face mask
  1 Dose
  Single Use Only

Distributed by

Enovachem™
PHARMACEUTICALS
Torrance, CA 90501

DOUBLEDEX KIT
dexamethasone sodium phosphate, povidine iodine kit
### Product Information

<table>
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<th>Product Type</th>
<th>Item Code (Source)</th>
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### Packaging

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<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<td>NDC:76420-766-01</td>
<td>1 in 1 CARTON; Type 1: Convenience Kit of Co-Package</td>
<td>05/23/2016</td>
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### Quantity of Parts

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<tr>
<th>Part #</th>
<th>Package Quantity</th>
<th>Total Product Quantity</th>
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<tbody>
<tr>
<td>Part 1</td>
<td>2 VIAL</td>
<td>2 mL</td>
</tr>
<tr>
<td>Part 2</td>
<td>1 PACKET</td>
<td>0.9 mL</td>
</tr>
<tr>
<td>Part 3</td>
<td>3 POUCH</td>
<td>15 mL</td>
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</table>

### Part 1 of 3

**DEXAMETHASONE SODIUM PHOSPHATE**
dexamethasone sodium phosphate injection, solution

### Product Information

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<th>Item Code (Source)</th>
<th>Route of Administration</th>
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<tr>
<td>NDC:63323-506</td>
<td>INTRAMUSCULAR, INTRAVENOUS</td>
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### Active Ingredient/Active Moiety

<table>
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<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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<tbody>
<tr>
<td>Dexamethasone Sodium Phosphate (UNII: A9376Y64P) (Dexamethasone - UNII:7S5I7G3JQL)</td>
<td>Dexamethasone Phosphate</td>
<td>10 mg in 1 mL</td>
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### Inactive Ingredients

<table>
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<tr>
<th>Ingredient Name</th>
<th>Strength</th>
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</thead>
<tbody>
<tr>
<td>Sodium Citrate</td>
<td></td>
</tr>
<tr>
<td>Citric Acid Monohydrate</td>
<td></td>
</tr>
<tr>
<td>Sodium Hydroxide</td>
<td></td>
</tr>
</tbody>
</table>

### Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1 mL</td>
<td>in 1 VIAL; Type 0: Not a Combination Product</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Povidone-Iodine

**Product Information**

<table>
<thead>
<tr>
<th>Item Code (Source)</th>
<th>Route of Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDC:67777-130</td>
<td>TOPICAL</td>
</tr>
</tbody>
</table>

**Active Ingredient/Active Moiety**

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Povidone-Iodine</strong> (UNII: 85H0HZU99M)</td>
<td>Iodine</td>
<td>10 mg in 1 mL</td>
</tr>
</tbody>
</table>

**Inactive Ingredients**

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nonoxynol-9</td>
<td></td>
</tr>
<tr>
<td>(UNII: 48Q180SH9T)</td>
<td></td>
</tr>
<tr>
<td>Water</td>
<td></td>
</tr>
<tr>
<td>(UNII: 059QF0KO0R)</td>
<td></td>
</tr>
</tbody>
</table>

**Packaging**

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td>0.9 mL in 1 PACKET; Type 0: Not a Combination Product</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Isopropyl Alcohol

**Product Information**

<table>
<thead>
<tr>
<th>Route of Administration</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>TOPICAL</td>
<td></td>
</tr>
</tbody>
</table>

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**Marketing Information**

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>OTC monograph final</td>
<td>part333C</td>
<td>05/10/2010</td>
<td></td>
</tr>
</tbody>
</table>
### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)</td>
<td>Isopropyl Alcohol</td>
<td>70 mL in 100 mL</td>
</tr>
</tbody>
</table>

### Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water (UNII: 059QF0KO0R)</td>
<td></td>
</tr>
</tbody>
</table>

### Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td>5 mL in 1 POUCH; Type 0: Not a Combination Product</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>OTC monograph not final</td>
<td>part333A</td>
<td>01/01/2007</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unapproved drug other</td>
<td></td>
<td>07/25/2014</td>
<td></td>
</tr>
</tbody>
</table>

**Labeler** - Asclemed USA, Inc. (059888437)

**Establishment**

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asclemed USA, Inc.</td>
<td></td>
<td>059888437</td>
<td>REPACK(76420-766)</td>
</tr>
</tbody>
</table>

Revised: 5/2016