**TOPIDEX- dexamethasone surgical combo kit**
**Topicare Management, LLC**

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## DEXAMETHASONE SODIUM PHOSPHATE

**For Intravenous or Intramuscular Use Only**

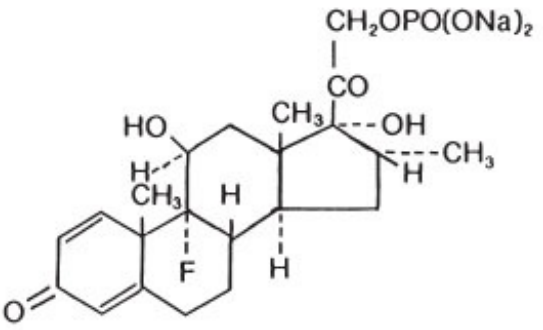
Rx only

## 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:




$C_{22}H_{28}FNa_2O_8P$ 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 cortisone 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.

**Serious Neurologic Adverse Reactions with Epidural Administration**

Serious neurologic events, some resulting in death, have been reported with epidural injection of corticosteroids. Specific events reported include, but are not limited to, spinal cord infarction, paraplegia, quadriplegia, cortical blindness, and stroke. These serious neurologic events have been reported with and without use of fluoroscopy. The safety and effectiveness of epidural administration of corticosteroids has not been established, and corticosteroids are not approved for this use.

**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 $LD_{50}$ of dexamethasone in female mice was 6.5 g/kg. The intravenous $LD_{50}$ 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:

| Author | Dosage |
|---|---|
| Cavanagh [1] | 3 mg/kg of body weight for 24 hours by constant intravenous infusion after an initial intravenous injection of 20 mg |
| Dietzman [2] | 2 to 6 mg/kg of body weight as a single intravenous injection |
| Frank [3] | 40 mg initially followed by repeat intravenous injection every 4 to 6 hours while shock persists |
| Oaks [4] | 40 mg initially followed by repeat intravenous injection every 2 to 6 hours while shock persists |
| Schumer [5] | 1 mg/kg of body weight as a single intravenous injection |

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:

| **Product No.** | **NDC. No.** | **Strength** | Vial Size |
|---|---|---|---|
| 500601 | 63323-506-01 | 10 mg per mL | 1 mL vial, 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:

| **Product No.** | **NDC. No.** | **Strength** | **Vial Size** |
|---|---|---|---|
| 501610 | 63323-516-10 | 100 mg per 10 mL (10 mg per mL) | 10 mL vial, packaged in tens. |

This container closure is not made with 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**


1. Cavanagh, D.; Singh, K.B.: Endotoxin shock in pregnancy and abortion, in: "Corticosteroids in the Treatment of Shock", Schumer, W.; Nyhus, L.M., Editors, Urbana, University of Illinois Press, 1970, pp. 86-96.
2. Dietzman, R.H.; Ersek, R.A.; Bloch, J.M.; Lilleheir, R.C.: High-output, low-resistance gram-negative septic shock in man, Angiology 20: 691-700, Dec. 1969.
3. Frank, E.: Clinical observations in shock and management (in: Shields, T.F., ed.: Symposium on current concepts and management of shock), J. Maine Med. Ass. 59: 195-200, Oct. 1968.
4. Oaks, W. W.; Cohen, H.E.: Endotoxin shock in the geriatric patient, Geriat. 22: 120-130, Mar. 1967.
5. Schumer, W.; Nyhus, L.M.: Corticosteroid effect on biochemical parameters of human oligemic shock, Arch. Surg. 100: 405-408, Apr. 1970.


**SPL UNCLASSIFIED SECTION**

FRESENIUS KABI
Fresenius Kabi USA, LLC
Lake Zurich, IL 60047

45955E

Revised: May 2014

**DEXAMETHASONE SODIUM PHOSPHATE INJECTION, USP 10 mg per mL**

**PACKAGE LABEL - PRINCIPAL DISPLAY - Dexamethasone 1 mL Vial Label**

**NDC** 63323-506-01

500601

**DEXAMETHASONE SODIUM PHOSPHATE INJECTION, USP**

**10 mg per mL**

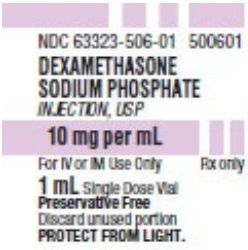
For IV or IM Use Only Rx only

**1 mL** Single Dose Vial

Preservative Free

Discard unused portion

PROTECT FROM LIGHT.




**POVIDONE IODINE**

Povidone-Iodine Swabsticks

For External Use Only

NDC# 67777-130-02

**ACTIVE INGREDIENT**

**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**

- **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.

**INDICATIONS & USAGE**

For use as an

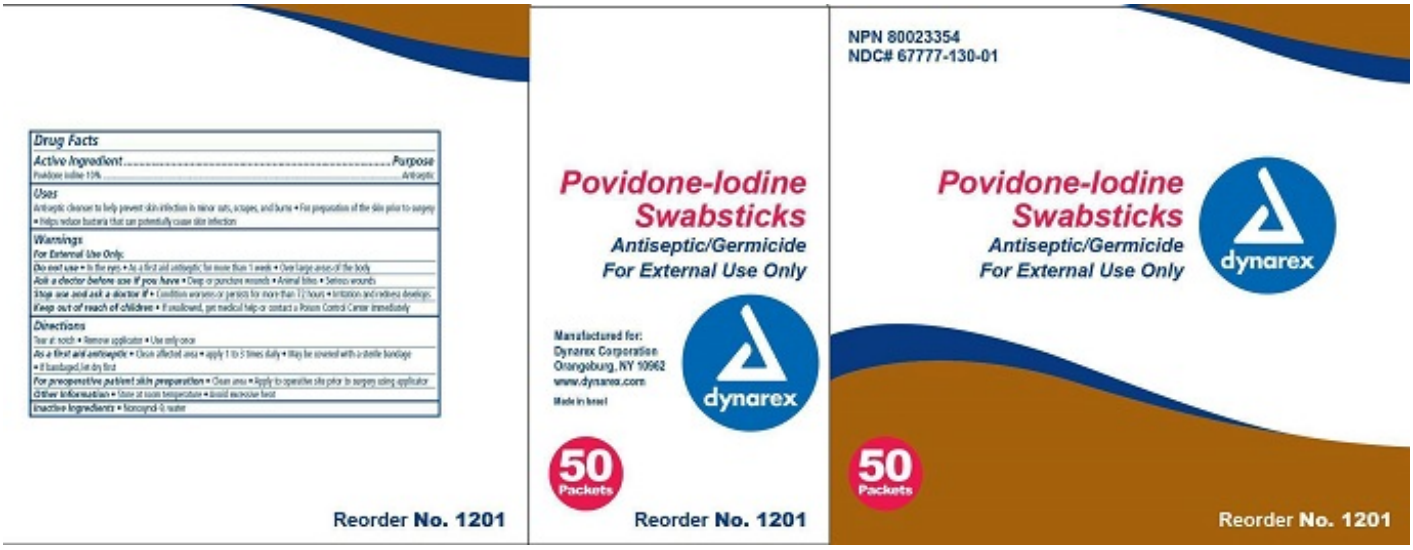
- first aid antiseptic
- pre-operative skin preperation

## INACTIVE INGREDIENTS

Inactive ingredients: nonoxynol-9, water

## PRINCIPAL DISPLAY PANEL

Povidone Iodine Swabsticks 1201 & 1202




## STERILE ALCOHOL PREP PAD

## ACTIVE INGREDIENT

**Active Ingredient.....Purpose**

Isopropyl Alcohol 70% v/v.....Antiseptic

## USE: ALCOHOL_PREP

For preparation of the skin prior to injection.

## WARNINGS

- For external use only
- Flammable, keep away from flame or fire
- Not for use with electrocautinary devices or procedures
- Do not use in eyes
- Sterile unless package is damaged or open.

## INDICATIONS AND USAGE

Stop use and ask a doctor if:

- Irritation or redness develops
- condition persists for more than 72 hours
- Cleansing of an injection site

## KEEP OUT OF REACH OF CHILDREN

In case of accidental ingestion, seek professional assistance or consult a poison control center

immediately.

## DIRECTIONS

Wipe injection site vigorously and discard

## OTHER INFORMATION

Store at room temperature: 15 deg C to 30 deg C 59 deg F to 86 deg F avoid excessive heat

## INACTIVE INGREDIENT

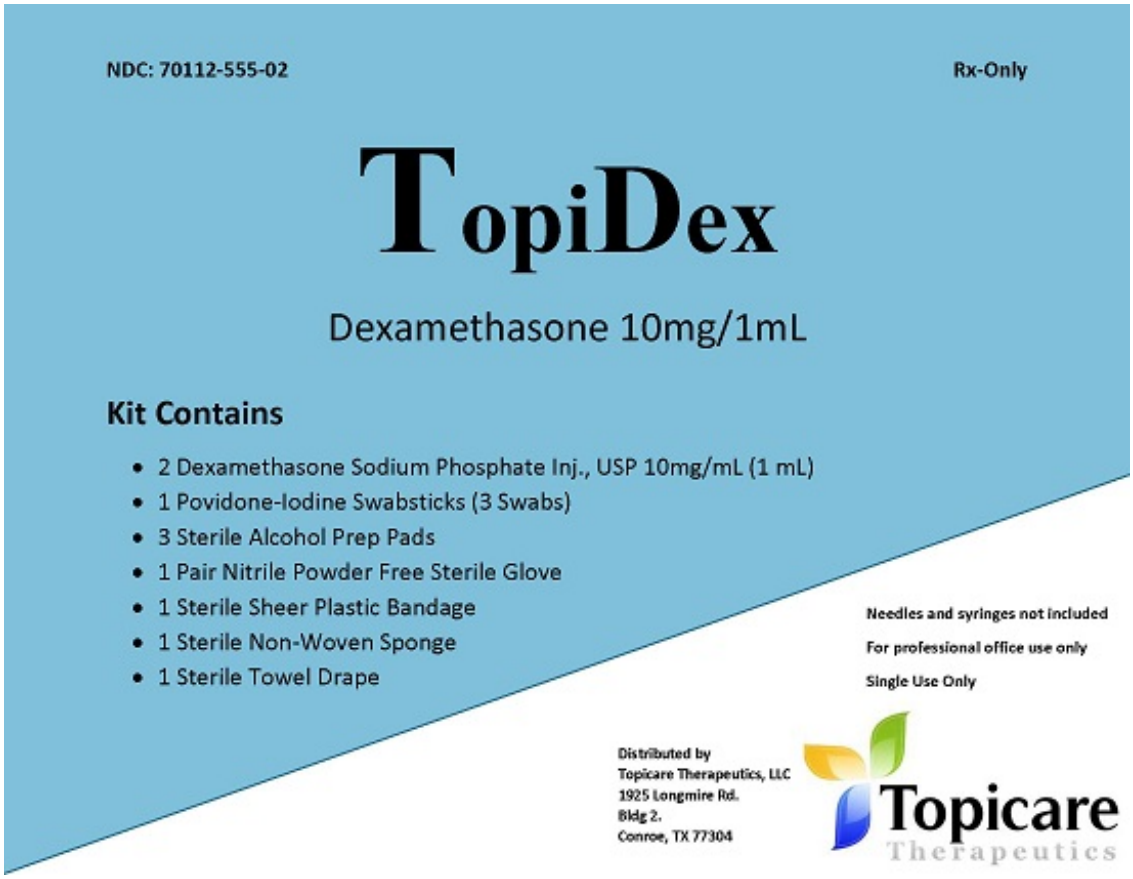
Inactive Ingredient

Water

## PRINCIPAL DISPLAY PANEL

Dynarex Sterile Alcohol Prep Pad


## TOPIDEX DEXAMETHASONE 10MG/1ML NDC# 70112-555-02




NDC# 70112-555-02

TopiDex

Rx-Only

Kit Contains:

- 2 Dexamethasone Sodium Phophate Inj., USP 10mg/mL (1 mL)
- 1 Povidone-Iodine Swabsticks (3 Swabs)
- 3 Sterile Alcohol Prep Pads
- 1 Pair Nitrile Powder Free Sterile Glove
- 1 Sterile Sheer Plastic Bandage
- 1 Sterile Non-Woven Sponge
- 1 Sterile Towel Drape

Needles and syringes not included

For professional office use only

Single Use Only

Distributed by

Topicare Therapeutics, LLC

1925 Longmire Rd.

Bldg 2

Conroe, TX 77304

| **TOPIDEX** |
| --- |
| dexamethasone surgical combo kit kit |

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:70112-555 |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:70112-555-02 | 1 in 1 BOX; Type 1: Convenience Kit of Co-Package | 04/16/2018 | |

| Quantity of Parts | | |
|---|---|---|
| **Part #** | **Package Quantity** | **Total Product Quantity** |
| **Part 1** | 2 VIAL | 2 mL |
| **Part 2** | 1 PACKET | 0.9 mL |
| **Part 3** | 3 POUCH | 1.65 mL |

## Part 1 of 3

# DEXAMETHASONE SODIUM PHOSPHATE

dexamethasone sodium phosphate injection, solution

| Product Information | |
|---|---|
| **Item Code (Source)** | NDC:63323-506 |
| **Route of Administration** | INTRAMUSCULAR, INTRAVENOUS |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **DEXAMETHASONE SODIUM PHOSPHATE** (UNII: AI9376Y64P) (DEXAMETHASONE - UNII:7S5I7G3JQL) | DEXAMETHASONE PHOSPHATE | 10 mg in 1 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **SODIUM HYDROXIDE** (UNII: 55X04QC32I) | |
| **SODIUM CITRATE** (UNII: 1Q73Q2JULR) | 24.5 mg in 1 mL |
| **CITRIC ACID MONOHYDRATE** (UNII: 2968PHW8QP) | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:63323-506-01 | 1 mL in 1 VIAL; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA040491 | 05/29/2003 | |

## Part 2 of 3

## POVIDINE IODINE

povidine iodine swab

### Product Information

| | |
|---|---|
| **Item Code (Source)** | NDC:67777-130 |
| **Route of Administration** | TOPICAL |

### Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **POVIDONE-IODINE** (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4) | IODINE | 10 mg in 1 mL |

### Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **NONOXYNOL-9** (UNII: 48Q180SH9T) | |
| **WATER** (UNII: 059QF0KO0R) | |

### Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:67777-130-02 | 0.9 mL in 1 PACKET; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph final | part333C | 05/10/2010 | |

## Part 3 of 3

## ALCOHOL PREP

isopropyl alcohol swab

### Product Information

| | |
|---|---|
| **Item Code (Source)** | NDC:67777-121 |

| | |
|---|---|
| **Route of Administration** | TOPICAL |

| **Active Ingredient/Active Moiety** | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **ISOPROPYL ALCOHOL** (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302) | ISOPROPYL ALCOHOL | 0.7 mL in 1 mL |

| **Inactive Ingredients** | |
|---|---|
| **Ingredient Name** | **Strength** |
| **WATER** (UNII: 059QF0KO0R) | |

| **Packaging** | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:67777-121-14 | 0.55 mL in 1 POUCH; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part333A | 07/01/2010 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA040491 | 04/16/2018 | |

## Labeler - Topicare Management, LLC (079902303)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Topicare Management, LLC | | 079902303 | label(70112-555) , manufacture(70112-555) |

Revised: 4/2018 Topicare Management, LLC