DEXAMETHASONE - dexamethasone elixir
ANI Pharmaceuticals, Inc.

DEXAMETHASONE ELIXIR, USP

DESCRIPTION

Each 5 mL (teaspoonful) contains:

Dexamethasone, USP..... 0.5 mg

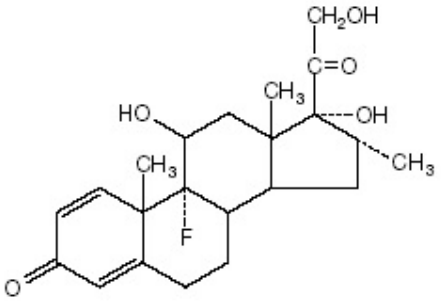
Also contains:

Benzoic Acid, USP..... 0.1% (as a preservative)

Alcohol.....5%

Inactive Ingredients: Artificial raspberry flavor, citric acid, edetate disodium, FD&C Red #40, propylene glycol, purified water, saccharin sodium, sorbitol solution.

Glucocorticoids are adrenocortical steroids, both naturally occurring and synthetic, which are readily absorbed from the gastrointestinal tract. Dexamethasone, a synthetic adrenocortical steroid, is a white to practically white, odorless, crystalline powder. It is stable in air. It is practically insoluble in water. The molecular weight is 392**.**47. It is designated chemically as 9-fluoro-11β,17,21-trihydroxy-16α-methylpregna-1,4-diene-3,20-dione. The molecular formula is $C_{22}H_{29}FO_5$ and the structural formula is:



CLINICAL PHARMACOLOGY

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 & USAGE

Allergic States

Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment: Atopic dermatitis, Bronchial asthma, Contact dermatitis, Drug hypersensitivity reactions, Seasonal or perennial allergic rhinitis, and Serum sickness.

Collagen Diseases

During an exacerbation or as maintenance therapy in selected cases of: Systemic lupus erythematosus, and Acute rheumatic carditis.

Dermatologic Diseases

Bullous dermatitis herpetiformis, Exfoliative dermatitis, Mycosis fungoides, Pemphigus, Severe erythema multiforme (Stevens-Johnson syndrome), Severe psoriasis, and Severe seborrheic dermatitis.

Edematous States

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

Endocrine Disorders

Primary or secondary adrenocortical insufficiency (hydrocortisone or cortisone is the first choice; synthetic analogs may be used in conjunction with mineralocorticoids where applicable; in infancy, mineralocorticoid supplementation is of particular importance), Congenital adrenal hyperplasia, Hypercalcemia associated with cancer, and Nonsuppurative thyroiditis.

Gastrointestinal diseases

To tide the patient over a critical period of the disease in: Ulcerative colitis, and Regional enteritis.

Hematologic Disorders

Idiopathic thrombocytopenic purpura in adults, Secondary thrombocytopenia in adults,

Acquired (autoimmune) hemolytic anemia, Erythroblastopenia (RBC anemia), and Congenital (erythroid) hypoplastic anemia.

Miscellaneous

Diagnostic testing of adrenocortical hyperfunction, Tuberculous meningitis with subarachnoid block or impending block when used concurrently with appropriate antituberculous chemotherapy, and Trichinosis with neurologic or myocardial involvement.

Neoplastic Diseases

For palliative management of: Leukemia and lymphomas in adults, and Acute leukemia of childhood.

Ophthalmic Diseases

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

Respiratory Diseases

Symptomatic sarcoidosis, Loeffler's syndrome not manageable by other means, Berylliosis, Fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate antituberculous chemotherapy, and Aspiration pneumonitis.

Rheumatic Disorders

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

CONTRAINDICATIONS

Contraindicated in patients with known systemic fungal infections (See **WARNINGS: Infections:***Fungal Infections*) and patients with a known sensitivity to this drug.

WARNINGS

In patients on corticosteroid therapy subjected to unusual stress, increased dosage of rapidly acting corticosteroids before, during, and after the stressful situation is indicated.

Immunosuppression and Increased Risk of Infection

Corticosteroids, including dexamethasone elixir, suppress the immune system and increase the risk of infection with any pathogen, including viral, bacterial, fungal, protozoan, or helminthic pathogens.

Corticosteroids can:

- Reduce resistance to new infections
- Exacerbate existing infections
- Increase the risk of disseminated infections
- Increase the risk of reactivation or exacerbation of latent infections
- Mask some signs of infection

Corticosteroid-associated infections can be mild but can be severe and at times fatal. The rate of infectious complications increases with increasing corticosteroid dosages.

Monitor for the development of infection and consider dexamethasone elixir withdrawal or dosage reduction as needed.

Tuberculosis

If dexamethasone elixir is used to treat a condition in patients with latent tuberculosis or tuberculin reactivity, reactivation of tuberculosis may occur. Closely monitor such patients for reactivation. During prolonged dexamethasone elixir therapy, patients with latent tuberculosis or tuberculin reactivity should receive chemoprophylaxis.

Varicella Zoster and Measles Viral Infections

Varicella and measles can have a serious or even fatal course in non-immune patients taking corticosteroids, including dexamethasone elixir. In corticosteroid-treated patients who have not had these diseases or are nonimmune, particular care should be taken to avoid exposure to varicella and measles:

- If a dexamethasone elixir-treated patient is exposed to varicella, prophylaxis with varicella zoster immune globulin may be indicated. If varicella develops, treatment with antiviral agents may be considered.
- If a dexamethasone elixir-treated patient is exposed to measles, prophylaxis with immunoglobulin may be indicated.

Hepatitis B Virus Reactivation

Hepatitis B virus reactivation can occur in patients who are hepatitis B carriers treated with immunosuppressive dosages of corticosteroids, including dexamethasone elixir. Reactivation can also occur infrequently in corticosteroid-treated patients who appear to have resolved hepatitis B infection.

Screen patients for hepatitis B infection before initiating immunosuppressive (e.g., prolonged) treatment with dexamethasone elixir. For patients who show evidence of hepatitis B infection, recommend consultation with physicians with expertise in managing hepatitis B regarding monitoring and consideration for hepatitis B antiviral therapy.

Fungal Infections

Corticosteroids, including dexamethasone elixir, may exacerbate systemic fungal infections; therefore, avoid dexamethasone elixir use in the presence of such infections unless dexamethasone elixir is needed to control drug reactions. For patients on chronic dexamethasone elixir therapy who develop systemic fungal infections, dexamethasone elixir withdrawal or dosage reduction is recommended.

Amebiasis

Corticosteroids, including dexamethasone elixir, may activate latent amebiasis. Therefore, it is recommended that latent amebiasis or active amebiasis be ruled out before initiating dexamethasone elixir in patients who have spent time in the tropics or patients with unexplained diarrhea.

Strongyloides Infestation

Corticosteroids, including dexamethasone elixir, should be used with great care in patients with known or suspected Strongyloides (threadworm) infestation. In such patients, corticosteroid-induced immunosuppression may lead to Strongyloides hyperinfection and dissemination with widespread larval migration, often accompanied by severe enterocolitis and potentially fatal gram-negative septicemia.

Cerebral Malaria

Avoid corticosteroids, including dexamethasone elixir, in patients with cerebral malaria.

Kaposi's Sarcoma

Kaposi's sarcoma has been reported to occur in patients receiving corticosteroid therapy, most often for chronic conditions. Discontinuation of corticosteroids may result in clinical improvement of Kaposi's sarcoma.

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.

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.

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.

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.

Average and large doses of hydrocortisone or cortisone 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.

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.

PRECAUTIONS

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 because of possible 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 should 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 cautiously 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, diverticulitis, fresh intestinal anastomoses, active or latent peptic ulcer, renal insufficiency, hypertension, osteoporosis, and myasthenia gravis. Fat embolism has been reported as a possible complication of hypercortisonism.

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

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

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.

INFORMATION FOR PATIENTS

Persons 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.

ADVERSE REACTIONS

Fluid and Electrolyte Disturbances:

Sodium retention, Fluid retention, Congestive heart failure in susceptible patients, Potassium loss, Hypokalemic alkalosis, and Hypertension.

Musculoskeletal:

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

Gastrointestinal:

Peptic ulcer with possible perforation and hemorrhage, Perforation of the small and large bowel, particularly in patients with inflammatory bowel disease, Pancreatitis, Abdominal distention, and Ulcerative esophagitis.

Dermatologic:

Impaired wound healing, Thin fragile skin, Petechiae and ecchymoses, Erythema, Increased sweating, May suppress reactions to skin tests, Other cutaneous reactions, such as allergic dermatitis, urticaria, and angioneurotic edema.

Neurologic:

Convulsions, Increased intracranial pressure with papilledema (pseudotumor cerebri) usually after treatment, Vertigo, Headache, and Psychic disturbances.

Endocrine:

Menstrual irregularities, Development of cushingoid state, Suppression of growth in children, 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, and Hirsutism.

Ophthalmic:

Posterior subcapsular cataracts, Increased intraocular pressure, Glaucoma, and Exophthalmos.

Metabolic:

Negative nitrogen balance due to protein catabolism

Cardiovascular:

Myocardial rupture following recent myocardial infarction (see **WARNINGS**)

Other:

Hypersensitivity, Thromboembolism, Weight gain, Increased appetite, Nausea, Malaise, and Hiccups.

To report SUSPECTED ADVERSE REACTIONS, contact ANI Pharmaceuticals, Inc. at 1-855-204-1431 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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.

DOSAGE & ADMINISTRATION

For oral administration

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

The initial dosage varies from 0.75 to 9 mg a day depending on the disease being treated. In less severe diseases doses lower than 0.75 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 satisfactory clinical response does not occur after a reasonable period of time, discontinue dexamethasone elixir 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. The following milligram equivalents facilitate changing to dexamethasone elixir from other glucocorticoids:

DEXAMETHASONE ELIXIR	**METHYLPREDNISOLONE AND TRIAMCINOLONE**	**PREDNISOLONE AND PREDNISONE**	**HYDROCORTISONE**	**CORTISONE**
0.75 mg =	4 mg =	5 mg =	20 mg =	25 mg

Dexamethasone suppression tests

1. Tests for Cushing's syndromeGive 1 mg of dexamethasone orally at 11:00 p.m. Blood is drawn for plasma cortisol determination at 8:00 a.m. the following morning.For greater accuracy, give 0.5 mg of dexamethasone orally every 6 hours for 48 hours. Twenty-four hour urine collections are made for determination of 17-hydroxycorticosteroid excretion.
2. Test to distinguish Cushing's syndrome due to pituitary ACTH excess from Cushing's syndrome due to other causes. Give 2 mg of dexamethasone orally every 6 hours for 48 hours. Twenty-four hour urine collections are made for determination of 17-hydroxycorticosteroid excretion

HOW SUPPLIED

Dexamethasone Elixir, USP 0.5 mg dexamethasone per 5 mL, is a pink-red liquid supplied in the following size:

8 fl oz (No Dropper) (237 mL) – NDC 70954-872-10

RECOMMENDED STORAGE

Store at 25ºC (77ºF); excursions permitted from 15º to 30º C (59º to 86ºF) [see USP Controlled Room Temperature].

KEEP TIGHTLY CLOSED. AVOID FREEZING.

Dispense in a tight, light-resistant container as defined in the USP.

Rx Only

Distributed by:

ANI Pharmaceuticals, Inc.

Baudette, MN 56623

Issued: 10/2025

LB4875-00

PI-1010

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Dexamethasone Elixir, USP 0.5 mg/5 mL

8 fl oz (237 mL) – NDC 70954-872-10

DEXAMETHASONE

dexamethasone elixir

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70954-872
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXAMETHASONE (UNII: 7S5I7G3JQL) (DEXAMETHASONE - UNII:7S5I7G3JQL)	DEXAMETHASONE	0.5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
ALCOHOL (UNII: 3K9958V90M)	

Product Characteristics

Color	PINK (pink-red)	**Score**	
Shape		**Size**	
Flavor	RASPBERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70954-872-10	1 in 1 CARTON	12/01/2025	
1		237 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA084754	12/01/2025	

Labeler - ANI Pharmaceuticals, Inc. (145588013)

Revised: 12/2025 ANI Pharmaceuticals, Inc.