EMERGENCY OVERVIEW
Each Dexamethasone Tablets USP intended for oral administration contains Dexamethasone and excipients generally considered non- toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

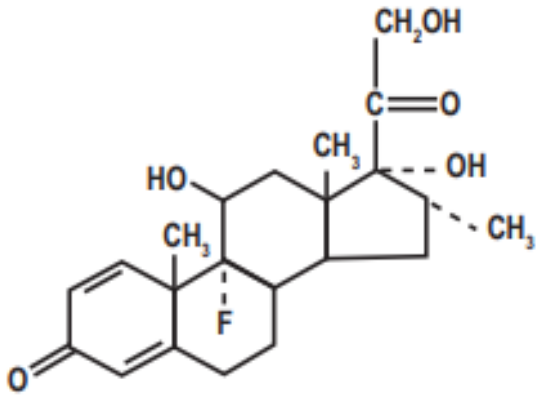
Section 1. IDENTIFICATION

Identification of the product

Product Name: Dexamethasone Tablets USP

Formula: $C_{22}H_{29}FO_5$

Chemical Name:



Manufacturer / Supplier identification

Company:	**Zydus Lifesciences Limited**
Address:	**Zydus Lifesciences Limited**, Swaraj Majra, Judi Kalan, Post - Baddi, Tehsil - Nalagarh, District - Solan, Himachal Pradesh 173205.
Contact for information:	Tel: +91-1795-246841 Fax: +91-1795-246842
Emergency Telephone No.	Tel: +91-1795-246841

Recommended use /
Therapeutic Category
INDICATIONS AND USAGE

Allergic States:	Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment in asthma, atopic dermatitis, contact dermatitis, drug hypersensitivity reactions, perennial or seasonal allergic rhinitis and serum sickness.
Dermatologic Diseases:	Bullous dermatitis herpetiformis, exfoliative erythroderma, mycosis fungoides, pemphigus and severe erythema multiforme.

Endocrine Disorders:	Primary or secondary adrenocortical insufficiency (hydrocortisone or cortisone is the drug of choice; may be used in conjunction with synthetic mineralocorticoid analogs 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 regional enteritis and ulcerative colitis.
Hematologic Disorders:	Acquired (autoimmune) hemolytic anemia, congenital (erythroid) hypoplastic anemia (Diamond-Blackfan anemia), idiopathic thrombocytopenic purpura in adults, pure red cell aplasia and selected cases of secondary thrombocytopenia.
Neoplastic Diseases:	For the palliative management of leukemias and lymphomas.
Nervous System	Acute exacerbations of multiple sclerosis, cerebral edema associated with primary or metastatic brain tumor, craniotomy or head injury.
Ophthalmic Diseases:	Sympathetic ophthalmia, temporal arteritis, uveitis and ocular inflammatory conditions unresponsive to topical corticosteroids.
Renal Diseases:	To induce a diuresis or remission of proteinuria in idiopathic nephrotic syndrome or that due to lupus erythematosus.
Respiratory Diseases:	Berylliosis, fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate antituberculous chemotherapy, idiopathic eosinophilic pneumonias, symptomatic sarcoidosis.
Rheumatic Disorders:	As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in acute gouty arthritis, acute rheumatic carditis, ankylosing spondylitis, psoriatic arthritis, rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy). For the treatment of dermatomyositis, polymyositis and systemic lupus erythematosus.
Restriction on Use / Contraindications:	It is contraindicated in patients with Systemic fungal infections and in patients who are hypersensitive to any components of these products.

Section 2. HAZARD(S) IDENTIFICATION

Dose and Administration

For Oral Administration The initial dosage varies from 0.75 mg to 9 mg a day depending on the disease being treated.

In the treatment of acute exacerbations of multiple sclerosis, daily doses of 30 mg of dexamethasone for a week followed by 4 mg to 12 mg every other day for one month have been shown to be effective.

In pediatric patients, the initial dose of dexamethasone may vary depending on the specific disease entity being treated. The range of initial doses is 0.02 mg/kg/day to 0.3 mg/kg/day in three or four divided doses (0.6 mg/m^2 bsa/day to 9 mg/m^2 bsa/day).

Adverse Effects

Allergic Reactions Anaphylactoid reaction, anaphylaxis, angioedema.

Cardiovascular Bradycardia, cardiac arrest, cardiac arrhythmias, cardiac enlargement, circulatory collapse, congestive heart failure, fat embolism, hypertension, hypertrophic cardiomyopathy in premature infants, myocardial rupture following recent myocardial infarction,

Dermatologic Acne, allergic dermatitis, dry scaly skin, ecchymoses and petechiae, erythema, impaired wound healing, increased sweating, rash, striae, suppression of reactions to skin tests, thin fragile skin, thinning scalp hair, urticaria,

Endocrine Decreased carbohydrate and glucose tolerance, development of cushingoid state, hyperglycemia, glycosuria, hirsutism, hypertrichosis, increased requirements for insulin or oral hypoglycemic agents in diabetes, manifestations of latent diabetes mellitus, menstrual irregularities, secondary adrenocortical and pituitary unresponsiveness (particularly in times of stress, as in trauma, surgery or illness), suppression of growth in pediatric patients.

Gastrointestinal	Abdominal distention, elevation in serum liver enzyme levels (usually reversible upon discontinuation), hepatomegaly, increased appetite, nausea, pancreatitis, peptic ulcer with possible perforation and hemorrhage, perforation of the small and large intestine (particularly in patients with inflammatory bowel disease), ulcerative esophagitis.
Musculoskeletal	Aseptic necrosis of femoral and humeral heads, loss of muscle mass, muscle weakness, osteoporosis, pathologic fracture of long bones, steroid myopathy, tendon rupture, vertebral compression fractures.
Neurological/Psychiatric	Convulsions, depression, emotional instability, euphoria, headache, increased intracranial pressure with papilledema (pseudotumor cerebri) usually following discontinuation of treatment, insomnia, mood swings, neuritis, neuropathy, paresthesia, personality changes, psychic disorders, vertigo.
Ophthalmic	Exophthalmos, glaucoma, increased intraocular pressure, posterior subcapsular cataracts, vision blurred.
Other	Abnormal fat deposits, decreased resistance to infection, hiccups, increased or decreased motility and number of spermatozoa, malaise, moon face, weight gain.
Over Dose Effect	Treatment of overdosage is by supportive and symptomatic therapy. In the case of acute overdosage, according to the patient's condition, supportive therapy may include gastric lavage or emesis.
Contraindications	Dexamethasone therapy is contraindicated in patients with Systemic fungal infections and in patients who are hypersensitive to any components of these products.
Pregnancy Comments	**Teratogenic Effects** Corticosteroids have been shown to be teratogenic in many species when given in doses equivalent to the human dose. Animal studies in which corticosteroids have been given to pregnant mice, rats and rabbits have yielded an increased incidence of cleft palate in the offspring. There are no adequate and well-controlled studies in pregnant women.

Corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Infants born to mothers who have received substantial doses of corticosteroids during pregnancy should be carefully observed for signs of hypoadrenalism.

Section 3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	Exposure Limit	CAS No.
Principle Component:		
Dexamethasone	Not Found	50-02-2
Inactive Ingredients:		
Corn Starch	Not Found	9005-25-8
Lactose Monohydrate	Not Found	10039-26-6
Ferric Oxide Yellow (0.5mg, 1mg, 4mg)	Not Found	1309-33-7
FD&C Blue NO. 1 Aluminium Lake (0.75mg, 4mg and 6mg)	Not Found	68921-42-6
Ferrosoferric Oxide (0.75mg)	Not Found	1317-61-9
FD & C Red No. 40 Aluminium Lake (1.5mg)	Not Found	25956-17-6
Ferric Oxide (Red) (1.5mg)	Not Found	1309-37-1
Sucrose	Not Found	57-50-1
Magnesium Stearate	Not Found	557-04-0

Section 4. FIRST-AID MEASURES

Inhalation Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention.

Skin Contact Immediately wash skin with soap and plenty of water. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.

Eye Contact Hold eyelids apart and flush eyes with plenty of water. Have eyes examined and tested by medical personnel.

Ingestion Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. Do NOT induce vomiting unless directed to do so by medical personnel. Get immediate medical attention.

Section 5. FIRST FIGHTING MEASURES

Flash Point	Not available
Extinguishing Media	Use alcohol-resistant foam, carbon dioxide, water, or dry chemical spray. Use water spray to cool fire-exposed containers.
Unusual Fire and Explosion Hazards	No unusual fire or explosion hazards noted.
Fire Fighting Instructions	Wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes

Section 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.
Methods and materials for containment and cleaning up	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

Section 7. HANDLING AND STORAGE

Storage	Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].
Precautions for safe handling	Avoid prolonged exposure. Avoid contact with eyes. Avoid release to environment. Use with adequate ventilation. When handling, use proper personal protective equipment. Wash thoroughly after handling. Keep container tightly closed when not in in use.

Section 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Respiratory Protection	Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. However, no personal respiratory protective equipment normally required.
Skin Protection	For prolonged or repeated skin contact use suitable protective gloves.
Eye/Face Protection	If contact is likely, safety glasses with side shields are recommended.
Protective Clothing	Protective clothing is not normally necessary; however, it is good practice to use apron.
Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	General ventilation normally adequate.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.
Engineering controls	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Section 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	Solid
Color	0.5mg and 1mg: Light yellow to yellow colored 0.75mg: Off-white to grey colored 1.5mg: Light-pink to pink colored 2mg: White to off white 4mg: Off-white to light green colored 6mg: Off-white to light blue colored
Odor	No unpleasant odor.
Pure/Mixture	Mixture

Section 10. STABILITY AND REACTIVITY

Stability	Normally stable but formation of toxic gases is possible during heating or in case of fire.
Incompatibility materials to avoid	Strong Oxidizing agents
Polymerization	Will not occur

Section 11. TOXILOGICAL INFORMATION

Ingestion	Toxic if Swallowed.
Inhalation	Due to lack of data, the classification is not possible.
Skin contact	Based on available data, the classification criteria are not met.
Eye contact	Causes eye irritation.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY

No adequate studies have been conducted in animals to determine whether corticosteroids have a potential for carcinogenesis or mutagenesis.

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

Section 12. ECOLOGICAL INFORMATION

Do not allow product to enter drinking water supplies, wastewater or soil.

Section 13. DISPOSAL CONSIDERATION

Disposal Recommendations	Dispose the waste in accordance with all applicable Federal, State and local laws.

Section 14. TRANSPORT INFORMATION

The product is not hazardous when shipping via air (IATA), ground (DOT), or sea (IMDG).

Section 15. REGULATORY INFORMATION

Generic Medicine, ANDA Number:

Dexamethasone Tablets USP 0.5mg, 0.75mg, 1.5mg, 4mg and 6mg: 216282

Dexamethasone Tablets USP 1mg: 216284

Dexamethasone Tablets USP 2mg: 216283

Section 16. OTHER INFORMATION

Date of issue: April 09, 2024 **Supersedes edition:** 00

The information presented in the safety data sheet is, to the best our knowledge, accurate and reliable. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.