or hypopigmentation.
Subcutaneous and cutaneous atrophy Sterile abscess Postinjection flare (following intra-articular use.)
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. Significant lethality was observed in female mice at single oral doses of 3630 mg/m^2 (1210 mg/kg) and single intravenous doses of 2382 mg/ m^2(794 mg/ kg)

Dosage & Administration
Dexamethasone Sodium Phosphate Injection USP, 4 mg / ml for intravenous, intramuscular, intra-articular, intralesional and soft tissue injection.
Dexamethasone Sodium Phosphate Injection USP 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. Solution used for intravenous administration or further dilution of this products 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 solution generally do not contain preservatives, mixture should be used within 24 hours.

Dosages requirements are variable and must be individualised on the basis of disease and the response of the patient.

Intravenous and Intramuscular injection.
The initial dosage of Dexamethasone Sodium Phosphate Injection USP injection varies from 0.5 to 9 mg a day depending on the disease being treated. In the less severe diseases doses lower than 0.5 mg may suffice, while in severe diseases doses higher than 9.0 mg may be required.

The initial dosages 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 USP injection and transfer the patient to other therapy.

After a favourable 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 remission or exacerbation 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

Storage
Store below 30ºC, protected from light.
Do not allow to freeze.

Presentation
Vials - 8mg/ 2ml. Pack of 25 x 2ml.

82/R01

Manufactured by:
KILITCH DRUGS (INDIA) LTD.
C-301/2, TTC Indl. Area, MIDC,
Pawane, India

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only.

DEXO

DEXAMETHASONE SODIUM PHOSPHATE INJECTION USP

FOR IM/IV/IA USE

8 mg / 2ml

Composition
Each ml contains :

Dexamethasone Sodium Phosphate USP equivalent to Dexamethasone Phosphate	4 mg
Methyl Paraben USP	0.15 % w/v
Propyl Paraben USP	0.02 % w/v
Water for Injection USP	q.s.

Description
Dexamethasone Sodium Phosphate, a synthetic adrenocortical steroid, is a white or slightly yellow, crystalline powder. It is freely soluble in water and is exceedingly hygroscopic.
Dexamethasone Sodium Phosphate injection is a sterile solution of Dexamethasone Sodium Phosphate, sealed under nitrogen, and is supplied as 4 mg/ ml in 2 ml vials / ampoules.

Action :
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 aderenocortical steroid therapy. Naturally occurring glucocorticoids (hydrocortisone and cortisone), which also have salt-retaining properties, are used as replacement therapy in adrenocortical deficiency state. 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 response to diverse stimuli. At equipotent anti-inflammatory doses, Dexamethasone almost completely lacks the sodium –retaining property of hydrocortisone and closely related derivaties of hydrocortisone.

Indications :
Endocrine disorders
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 adrenocortial reserve in doubtful. Shock unresponsive to conventional therapy when adrenocortial insufficiency exists or is suspected.

Rheumatic disorders
As adjunctive therapy for short – term administration.
- Rheumatoid arthritis (selected cases may require low dose maintenance therapy)
- Acute and subacute bursitis
- Epicondylitis
- Acute nonspecific tenosynovitis
- Acute gouty arthritis
- Ankylosing spondylitis

Collagen disorders
During exacerbation or as maintenance therapy in selected cases of
- Systemic lupus erythematosus
- Acute rheumatic carditis

Dermatologic diseases
- Pemphigus
- Severe erythema multiforne (stevens- Johnson syndrome)
- Exfoliative dermatitis
- Bulbous dermatitis herpetiformis
- Severe seborrheic dermatitis
- Severe psoriasis

Allergic states
Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment in
- Bronchial asthma
- Contact dermatitis

Size : 170 x 130 MM (Front/Back)

Atopic dermatitis
Serum sickness
Seasonal or perennial allergic rhinitis
Urticarial transfusion reactions
Acute noninfectious laryngeal edema (epinephrine is the drug of first choice)
Drug hypersensentitive reactions.

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
Sympathetic Ophthalmia
Anterior segment inflammation
Allegric conjunctivitis
Keratitis
Allergic corneal marginal ulcers.

Gastrointestinal diseases
To tide the patient over a critical period of the disease in :
Ulcerative colitis (systemic therapy)
Regional entries (systemic therapy)

Respiratory diseases
Symptomatic sarcoidosis
Berylliosis
Fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate antituberculosis chemotherapy
Loeffler's syndrome not manageable by other means
Aspiration pneumonitis

Hematologic disorders
Acquired (auto immune) hemolytic anaemia
Idiopathic thrombocytopenic purpura in adults (I.V. only I. M. administration is contraindicated)
Secondary thrombocytopenia in adults
Erythroblastopenia (RBC anaemia)
Congenital (erythoid) hypoplastic anaemia.

Warnings & Precautions:
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. Analphylactoid and hypersensitivity reactions have been reported for injection Dexamethasone Sodium Phosphate Injection USP. Following prolonged therapy, withdrawal of corticosteroid may result in symptoms of the corticosteroid withdrawal syndrome including fever, mylagia, arthralgia, and malaise. This may occur in patients even without evidence of adrenal insufficiency.

There is an enhanced effect of corticosteroids in patients with hypothyrodism and in those with cirrhosis. Corticosteroids should be used cautiously in patients with occular Herpes simplex for fear of corneal perforation.

The lowest possible dose of corticosteroids 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 manifestation. 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, also in diverticulitis, fresh intestinal anastomoses, active or latent peptic ulcers.

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 sign of hypoadrenalism.

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
Aspectic necrosis of femoral and humeral heads
Pathologic fracture of long bones
Tendon ruptures

Gastrointestinal
Peptic ulcer with possible subsequent perforation and heamorrhage
Perforation of the small and large bowel, particularly in patients with inflammatory bowel diseases
Pancreatitis
Abdominal distention
Ulcerative esophagitis

Dermatologic
Impaired wound healing
Thin fragile skin
Petechiae and ecchymoses
Erythema
Increased sweating
May suppress reaction to skin tests
Burning or tingling, especially in the perineal area. (after I. V. 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 children
Secondary adrenocortical and pituitary unresponsiveness particularly in times of stress, as in trauma, surgery, or illness.
Decreased carbohydrate tolerance
Manifestation of latent diabetes mellitus
Increased requirements for insulin or oral hypoglycemic agents in diabetes
Hirsutism

Ophthalmic
Posterior subcapsular cataracts
Increased intraocular pressure
Glaucoma
Exophthalmos

Metabolic
Negative nitrogen balance due to protein catabolism

Cardiovascular
Myocardial rupture following recent myocardial infraction.

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

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

Rare instances of blindness associated with intralesional therapy around the face and head Hyperpigmentation