Deflacort™

Deflazacort

Active Ingredient
Deflazacort

Indication
•Anaphylaxis, asthma, severe hypersensitivity reactions •Rheumatoid arthritis, juvenile chronic arthritis, polymyalgia rheumatica •Systemic lupus erythematosus, dermatomyositis, mixed connective tissue disease (other than systemic sclerosis), polyarteritis nodosa, sarcoidosis •Pemphigus, bullous pemphigoid, pyoderma gangrenosum •Minimal change nephrotic syndrome, acute interstitial nephritis •Rheumatic carditis •Ulcerative colitis, Crohn's disease
•Uveitis, optic neuritis •Autoimmune haemolytic anaemia, idiopathic thrombocytopenic purpura •Acute & lymphatic leukaemia, malignant lymphoma, multiple myeloma •Immune suppression in transplantation

Dosage & Administration
Adults: For acute disorders, up to 120 mg/day Deflacort™ (Deflazacort) may need to be given initially. Maintenance doses in most conditions are within the range 3 - 18 mg/day. Rheumatoid arthritis: The maintenance dose is usually within the range 3 - 18 mg/day. The smallest effective dose should be used & increased if necessary. Bronchial asthma: In the treatment of an acute attack, high doses of 48-72 mg/day may be needed depending on severity & gradually reduced once the attack has been controlled. For maintenance in chronic asthma, doses should be titrated to the lowest dose that controls symptoms. Other conditions: The dose of Deflacort™ (Deflazacort) depends on clinical need titrated to the lowest effective dose for maintenance. Starting doses may be estimated on the basis of ratio of 5mg prednisone or prednisolone to 6mg.
Hepatic Impairment: In patients with hepatic impairment, blood levels of may be increased. Therefore the dose of Deflacort™ (Deflazacort) should be carefully monitored & adjusted to the minimum effective dose. Renal Impairment- In renally impaired patients, no special precautions other than those usually adopted in patients receiving glucocorticoid therapy are necessary.
Elderly
In elderly patients, no special precautions other than those usually adopted in patients receiving glucocorticoid therapy are necessary. The common adverse effects of systemic corticosteroids may be associated with more serious consequences in old age.
Children
There has been limited exposure of children to Deflazacort in clinical trials.
In children, the indications for glucocorticoids are the same as for adults, but it is important that the lowest effective dosage is used. Alternate day administration may be appropriate.
Doses of Deflacort™ (Deflazacort) usually lie in the range 0.25 - 1.5 mg/kg/day. The following ranges provide general guidance:
Juvenile chronic arthritis: The usual maintenance dose is between 0.25 - 1.0 mg/kg/day.
Nephrotic syndrome: Initial dose of usually 1.5 mg/kg/day followed by down titration according to clinical need.
Bronchial asthma: On the basis of the potency ratio, the initial dose should be between 0.25 - 1.0 mg/kg on alternate days.

Contraindication & Precaution
Hypersensitivity to or any of the ingredients. Patients receiving live virus immunisation.
The following clinical conditions require special caution & frequent patient monitoring is necessary: • A Cardiac disease or congestive heart failure (except in the presence of active rheumatic carditis), hypertension, thromboembolic disorders. Glucocorticoids can cause salt & water retention & increased excretion of potassium. Dietary salt restriction & potassium supplementation may be necessary. • Gastritis or oesophagitis, diverticulitis, ulcerative colitis if there is probability of impending perforation, abscess or pyogenic infections, fresh intestinal anastomosis, active or latent peptic ulcer. • Diabetes mellitus or a family history, osteoporosis, myasthenia gravis, renal insufficiency. • Emotional instability or psychotic tendency, epilepsy. • Previous corticosteroid-induced myopathy. • Liver failure. • Hypothyroidism & cirrhosis, which may increase glucocorticoid effect.
•Ocular herpes simplex because of possible corneal perforation.

Side Effect
The incidence of predictable undesirable effects, including hypothalamic-pituitary-adrenal suppression correlates with the relative potency of the drug, dosage, timing of administration & the duration of treatment. •Musculoskeletal such as osteoporosis etc. •Fluid & electrolyte disturbance such as oedema & heart failure etc. •Ophthalmic such as glaucoma, papilloedema etc. •Gastrointestinal such as dyspepsia, peptic ulceration etc. •General such as anaphylaxis & rare incidence of benign intracranial hypertension. Withdrawal symptoms & signs .Too rapid a reduction of corticosteroid dosage following prolonged treatment can lead to acute adrenal insufficiency, hypotension & death.

Drug Interaction
Rifampicin, rifabutin, carbamazepine, phenobarbital, phenytoin, primidone, aminoglutethimide, ketoconazole, insulin, acetazolamide & carbenoxolone may interact with Deflazacort.

The following types of medicine may
interact with Deflazacort
Estrogens, hypoglycaemics, antihypertensives, diuretics, coumarin anticoagulants, nondepolarising, muscle relaxants, salicylates, antacids, oral contraceptives, vaccines, liver enzyme inducers, liver enzyme inhibitors, betaagonists & xanthines.

Use in Pregnancy & Lactation
Pregnancy – Deflazacort does cross the placenta. However, when administered for prolonged periods or repeatedly during pregnancy, corticosteroids may increase the risk of intra-uterine growth retardation. As with all drugs, corticosteroids should only be prescribed when the benefits to the mother & child outweigh the risks.
Nursing Mother – Corticosteroids are excreted in breast milk, although no data are available for Deflazacort. Doses of up to 50 mg daily of Deflazacort are unlikely to cause systemic effects in the infant. Infants of mothers taking higher doses than this may have a degree of adrenal suppression but the benefits of breast feeding are likely to outweigh any theoretical risk.

Use in Children
Corticosteroids cause dose-related growth retardation in infancy, childhood & adolescence which may be irreversible.

Preparation
6 mg, 24 mg, 30 mg tablet & 60 ml suspension.

Manufactured by

SQUARE
PHARMACEUTICALS LTD.
BANGLADESH