

Deflacort™

Deflazacort INN

COMPOSITION

- Deflacort™ 6:** Each tablet contains Deflazacort INN 6 mg.
Deflacort™ 18: Each tablet contains Deflazacort INN 18 mg.
Deflacort™ 24: Each tablet contains Deflazacort INN 24 mg.
Deflacort™ 30: Each tablet contains Deflazacort INN 30 mg.
Deflacort™ Suspension: Each 5 ml suspension contains Deflazacort INN 6 mg.

Deflacort™ (Deflazacort) is a glucocorticoid derived from Prednisolone and 6 mg of Deflazacort has approximately the same anti-inflammatory potency as 5 mg Prednisolone or prednisone.

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), polyarthritis 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 and 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 and 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 and 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 5 mg prednisone or prednisolone to 6 mg.

Hepatic Impairment

In patients with hepatic impairment, blood levels of may be increased. Therefore the dose of **Deflacort™** (Deflazacort) should be carefully monitored and 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.

DEFLAZACORT WITHDRAWAL

In patients who have received more than physiological doses of systemic corticosteroids (approximately 9 mg per day or equivalent) for greater than 3 weeks, withdrawal should not be abrupt. How dose reduction should be carried out depends largely on whether the disease is likely to relapse as the dose of systemic corticosteroids is reduced.

CONTRAINDICATION

Hypersensitivity to or any of the ingredients. Patients receiving live virus immunisation.

PRECAUTIONS

The following clinical conditions require special caution and frequent patient monitoring is necessary:-

- Cardiac disease or congestive heart failure (except in the presence of active rheumatic carditis), hypertension, thromboembolic disorders. Glucocorticoids can cause salt and water retention and increased excretion of potassium. Dietary salt restriction and 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 and cirrhosis, which may increase glucocorticoid effect.
- Ocular herpes simplex because of possible corneal perforation.

ADVERSE EFFECTS

GI disturbances, musculoskeletal, endocrine, neuropsychiatric, ophthalmic, fluid and electrolyte disturbances; susceptible to infection, impaired healing, hypersensitivity, skin atrophy, striae, telangiectasia, acne, myocardial rupture following recent MI, thromboembolism.

USE IN PREGNANCY AND 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 and 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.

STORAGE

Store in a cool (below 25°C) and dry place, protect from light & moisture. Keep out of the reach of children.

HOW SUPPLIED

- Deflacort™ 6:** Each box contains 50 tablets in blister packs.
Deflacort™ 18: Each box contains 20 tablets in blister packs.
Deflacort™ 24: Each box contains 20 tablets in blister packs.
Deflacort™ 30: Each box contains 10 tablets in blister packs.
Deflacort™ Suspension: Each bottle containing 60 ml suspension with a measuring cup.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH