

#### Composition

**Zacort 6 Tablet:** Each film coated tablet contains Deflazacort INN 6 mg.  
**Zacort 24 Tablet:** Each film coated tablet contains Deflazacort INN 24 mg.  
**Zacort 30 Tablet:** Each film coated tablet contains Deflazacort INN 30 mg.  
**Zacort Suspension 60 ml:** Each 5 ml suspension contains Deflazacort INN 6 mg.

#### Pharmacology

It provides anti-inflammatory action by inhibiting Phospholipase A2 enzyme which is responsible for prostaglandin synthesis. Besides Deflazacort decreases the release of certain chemicals that are important in the immune system. By decreasing the release of these chemicals Deflazacort provides immunosuppressive action.

#### Indication

It is indicated for-

- Anaphylaxis, asthma, severe hypersensitivity reactions
- Rheumatoid arthritis, juvenile chronic arthritis, polymyalgia rheumatic
- 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 hemolytic anemia, idiopathic thrombocytopenic purpura
- Acute and lymphatic leukemia, malignant lymphoma, multiple myeloma
- Immune suppression in transplantation

#### Dose and Administration

a) *Route of administration:* Oral.

*Adults:*

- For acute disorders: Up to 120 mg/day Deflazacort may need to be given initially. Maintenance doses in most conditions are within the range of 3-18 mg/day.
- Rheumatoid arthritis: The maintenance dose is usually within the range of 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 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. *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 Deflazacort usually lie in the range 0.25-1.5 mg/kg/day.

*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.

#### Contra-indication

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

#### Warning & Precaution

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 esophagitis, diverticulitis, ulcerative colitis if there is the probability of impending perforation, abscess or pyogenic infections, fresh intestinal anastomosis, active or latent peptic ulcer.
- Diabetes mellitus or 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 the glucocorticoid effect.
- Ocular herpes simplex because of possible corneal perforation.

#### Side effects

a) *Common:* 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.

b) *Rare:* Difficulty with swallowing, dizziness, fast heartbeat, itching or rash, puffiness or swelling of the eyelids, face, lips or tongue

#### Use in Pregnancy & Lactation

*Pregnancy:* It does cross the placenta. However, when administered for prolonged periods or repeatedly during pregnancy, corticosteroids may increase the risk of intrauterine 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 breastfeeding are likely to outweigh any theoretical risk.

#### Use in Children & Adolescent

See the dose and administration.

#### Drug Interaction

Moderate or strong CYP3A4 inhibitors: Give one third of the recommended dosage of Deflazacort. Avoid use of moderate or strong CYP3A4 inducers with Deflazacort as they may reduce efficacy.

#### Overdose

Treatment of acute overdosage is by immediate gastric lavage or emesis followed by supportive and symptomatic therapy. For chronic overdosage in the face of severe disease requiring continuous steroid therapy, the dosage of Deflazacort may be reduced temporarily, or alternate day treatment may be introduced.

#### Storage

Store below 30°C. Protect from light and moisture. Keep all medicines out of reach of children.

#### Packing

**Zacort 6 Tablet:** Each box contains 30 (3X10's) tablets in alu-alu blister pack.  
**Zacort 24 Tablet:** Each box contains 20 (2X10's) tablets in alu-alu blister pack.  
**Zacort 30 Tablet:** Each box contains 10 (1X10's) tablets in alu-alu blister pack.  
**Zacort Suspension 60 ml:** Each box contains of 60 ml suspension with a measuring cup.