# Refla™

*Deflazacort*

**Composition:**
**Refla**™ Tablet: Each tablet contains Deflazacort INN 6 mg.

**Description:**
**Refla**™ (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. Its anti-inflammatory and immunosuppressive effects are used in treating a variety of diseases.

**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
- Ulcerative colitis, Crohn's disease
- 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 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 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, plasma levels of blood may be increased. Therefore the dose of 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 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.

*OR AS DIRECTED BY THE PHYSICIAN.*

**Side 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.

**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.
- Diabetes mellitus or a family history, osteoporosis, myasthenia gravis, renal insufficiency

**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 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.

**Drug Interactions:**
Concurrent use of glucocorticoids and oral contraceptives should be closely monitored as plasma levels of glucocorticoids may be increased. This effect may be due to a change in metabolism or binding to serum proteins. Antacids may reduce bioavailability; leave at least 2 hours between administration of Deflazacort and antacids.

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

**Storage Condition:**
Keep in a cool and dry place below 30° C, protect from light. Keep out of the reach of children.

**Presentation:**
**Refla**™ Tablet: Each box contains 3×10's tablets in blister pack.