DEFLAZEN

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for DEFLAZEN [Deflazacort tablets 6mg & 30mg] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Deflazacort is a glucocorticoid, its anti-inflammatory and immunosuppressive effects are used in treating a variety of diseases. **INDICATION:** Indicated for the treatment of severe asthma and rheumatoid arthritis when glucocorticoid therapy is warranted. **DOSAGE AND ADMINISTRATION**: Adult: For acute disorders: initially up to 120 mg/day; Maintenance dose- 3-18 mg/day (for most conditions); Bronchial asthma: in case of acute attack high doses of 48-72 mg/day; Children: 0.25-1.5 mg/kg/day; Juvenile chronic arthritis: Maintenance dose- 0.25-1.0 mg/kg/day; Bronchial asthma: Initial dose: 0.25-1.0 mg/kg on alternate day. The dose of deflazacort should be carefully monitored and adjusted to the minimum effective dose in patients with hepatic impairment. **CONTRAINDICATION:** Hypersensitivity to drug or any ingredients, systemic infection unless specific anti-infective therapy employed, patient receiving live virus immunisation. **WARNINGS & PRECAUTIONS**: Patients with rare hereditary problems of galactose intolerance should not take medicine; Adrenal cortical atrophy develops during prolonged therapy; Suppression of the inflammatory response and immune function increases susceptibility to infections; Prolonged use of glucocorticoids produce posterior sub capsular cataracts, glaucoma with damage to the optic nerves; Use in management of active tuberculosis should be restricted only to fulminating and disseminated tuberculosis with appropriate antitubercular regimen; Special caution and frequent patient monitoring in cardiac disease or congestive heart failure, hypertension, thromboembolic disorders, gastritis or oesophagitis, diverticulitis, ulcerative colitis, diabetes mellitus, osteoporosis, myasthenia gravis, renal insufficiency, psychotic tendency, epilepsy, liver failure, hypothyroidism, cirrhosis and ocular herpes simplex. **DRUG INTERACTIONS**: Interacts with liver enzyme inducers (e.g. rifampicin, rifabutin, carbamazepine, phenobarbitone, phenytoin, primidone and aminoglutethimide), liver enzyme inhibitors (e.g. ketoconazole), estrogens, hypoglycaemic agents (including insulin), antihypertensives, diuretics, acetazolamide, loop diuretics, thiazide diuretics, carbenoxolone, coumarin anticoagulants, non-depolarising muscle relaxants, salicylates, oral contraceptives and antacids. **ADVERSE REACTIONS**: Suppression of hypothalamic pituitary-adrenal axis, growth suppression in infancy, childhood and adolescence, menstrual irregularity and amenorrhoea, Cushingoid facies, hirsutism, weight gain, impaired carbohydrate tolerance with increased requirement for anti-diabetic therapy, negative protein and calcium balance, increased appetite, osteoporosis, vertebral and long bone fractures, avascular osteonecrosis, tendon rupture muscle wasting, negative nitrogen balance, sodium and water retention with hypertension, oedema and heart failure, potassium loss, hypokalaemic alkalosis, headache, vertigo, euphoria, psychological dependence, hypomania or depression, insomnia, restlessness and aggravation of schizophrenia; Increased intra-ocular pressure, glaucoma, papilloedema, posterior subcapsular cataracts especially in children, corneal or scleral thinning, and exacerbation of ophthalmic viral orfungal diseases, dyspepsia, peptic ulceration; acute pancreatitis, candidiasis, impaired healing, skin atrophy, bruising, telangiectasia, striae, acne, hypersensitivity reaction, leucocytosis, thromboembolism, intracranial hypertension and withdrawal symptoms.

MARKETED BY:

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(Additional information is available on request)