Defzort®
Deflazacort

Description
Defzort® is a preparation of Deflazacort which is a glucocorticoid derived from prednisolone. Deflazacort works by acting within the cells to prevent the release of certain chemicals that are important in the immune system. By decreasing the release of these chemicals in particular area, inflammation is reduced. This, along with the decrease in inflammatory chemicals, can prevent the rejection of organ transplants. Deflazacort suppresses the immune system and so can be used to treat autoimmune diseases.

Indications and usage
Defzort® is indicated in the treatment of -
- 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 and lymphatic leukaemia, malignant lymphoma, multiple myeloma.
- Immune suppression in transplantation.

Dosage and administration
Adults
Acute disorders: In the treatment of acute disorders, up to 120 mg/day 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 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 Deflazacort.

Hepatic Impairment: In patients with hepatic impairment, blood levels of may be increased. Therefore the dose 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.

**Children**
Doses usually lie in the range 0.25 - 1.5 mg/kg/day. Alternate day administration may be appropriate. However, glucocorticoids cause growth retardation in infancy, childhood & adolescence, therefore long-term administration of pharmacological doses should be avoided.

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.

**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.

- **Lactation:** 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.

**Side effects**
Deflazacort is associated with side effects like skin lesions such as acne, bruises or stretch marks, recurrent infections, stomach upset, muscle or bone weakness, increased blood sugar, increased appetite and weight gain, Cushing’s syndrome, menstrual cycle irregularities or hirsutism.

**Contraindications**
Deflazacort is contraindicated in patients with known hypersensitivity to Deflazacort or any of the ingredients and patients receiving live virus immunization.

**Precautions**
Deflazacort should be used with caution in patients with adrenal suppression and infection (e.g., chickenpox, shingles, measles), elderly (close supervision required particularly on longterm treatment); frequent monitoring required if history of tuberculosis (or X-ray changes), hypertension, recent myocardial infarction (rupture reported), congestive heart failure, liver failure, renal impairment, diabetes mellitus including family history, osteoporosis (postmenopausal women at special risk), glaucoma (including family history), severe effective disorders (particularly if history of steroid-induced psychosis), epilepsy, peptic ulcer, hypothyroidism.

**Warnings**
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. Avoid long-term use of this
medication and abrupt withdrawal. Avoid contact with people with infections that can be spread to others. Patients may develop with increased risk of confusion, irritability, nightmares, difficulty sleeping, mood changes and depression, and suffer from delusions and suicidal thoughts if it is taken excess.

**Drug interactions**
The same precautions should be exercised as for other glucocorticoids. Deflazacort is metabolised in the liver. It is recommended to increase the maintenance dose of Deflazacort if drugs which are liver enzyme inducers are co-administered, e.g. rifampicin, rifabutin, carbamazepine, phenobarbitone, phenytoin, primidone and aminoglutethimide. For drugs which inhibit liver enzymes, e.g. ketoconazole it may be possible to reduce the maintenance dose of Deflazacort. In patients taking estrogens, corticosteroid requirements may be reduced. The desired effects of hypoglycaemic agents (including insulin), anti-hypertensives and diuretics are antagonised by corticosteroids and the hypokalaemic effects of acetazolamide, loop diuretics, thiazide diuretics, beta 2-agonists, xanthines and carbenoxolone are enhanced. The efficacy of coumarin anticoagulants may be enhanced by concurrent corticosteroid therapy and close monitoring of the INR or prothrombin time is required to avoid spontaneous bleeding. In patients treated with systemic corticosteroids, use of non-depolarising muscle relaxants can result in prolonged relaxation and acute myopathy. Risk factors for this include prolonged and high dose corticosteroid treatment, and prolonged duration of muscle paralysis. This interaction is more likely following prolonged ventilation (such as in the ITU setting). The renal clearance of salicylates is increased by corticosteroids and steroid withdrawal may result in salicylate intoxication. As glucocorticoids can suppress the normal responses of the body to attack by micro-organisms, it is important to ensure that any anti-infective therapy is effective and it is recommended to monitor patients closely. 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.

**Overdose**
It is unlikely that treatment is needed in cases of acute overdosage.

**Pharmaceutical precautions**
Keep away from the reach of the children. Store in a cool (below 25°C) and dry place protected from light. To be taken and sold only on the prescription of a registered physician.

**Presentation**
**Defzort®** tablet: Each coated tablet contains Deflazacort INN 6 mg.

**Package quantities**
**Defzort®** tablet: Carton of 30 tablets in blister packs.

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