

Imucort

Deflazacort INN

Composition

Imucort 6 Tablet: Each tablet contains Deflazacort INN 6 mg

Imucort 24 Tablet : Each tablet contains Deflazacort INN 24 mg

Imucort Oral Suspension : Each 5 ml oral suspension contains Deflazacort INN 6 mg

Description

Deflazacort is a corticosteroid prodrug, whose active metabolite, 21-desDFZ, acts through the glucocorticoid receptor to exert anti-inflammatory and immunosuppressive effects. Its anti-inflammatory and immunosuppressive effects are used in treating a variety of diseases and are comparable to other anti-inflammatory steroids. Clinical studies have indicated that the average potency ratio of Deflazacort to prednisolone is 0.69:0.89.

Indications

It is indicated for the treatment of Duchenne muscular dystrophy (DMD), in patients 5 years of age and older and in wide range of conditions which may sometimes need treatment with glucocorticoids. The indications include:

- 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 & administration

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 dose 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 deflazacort.

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.

Children:

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 deflazacort on alternate days.

Side effects

The most common adverse reactions are Cushingoid appearance, weight increased, increased appetite, upper respiratory tract infection, cough, pollakiuria, hirsutism, central obesity and nasopharyngitis.

Contraindications

Systemic infection unless specific anti-infective therapy is employed. Hypersensitivity to deflazacort or any of the ingredients. Patients receiving live virus immunization.

Precaution & Warning

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
- 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
- Emotional instability or psychotic tendency
- Previous corticosteroid induced myopathy
- Hypothyroidism and cirrhosis, which may increase glucocorticoid effect
- Ocular herpes simplex because of possible corneal perforation

Drug Interactions

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 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.

Use in pregnancy: Deflazacort does cross the placenta. 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.

Use in lactation: Corticosteroids are excreted in breast milk. Doses up to 50 mg daily of Deflazacort are unlikely to cause systemic effects in the infant.

Storage

Store in a cool and dry place, protect from light. Keep out of the reach of children.

Packaging

Imucort 6 Tablet : Each box contains 3x10's tablets in blister pack.

Imucort 24 Tablet : Each box contains 2x10's tablets in blister pack.

Imucort Oral Suspension : Each bottle contains 60 ml of Deflazacort oral suspension.

Manufactured by

ZISKA Ziska Pharmaceuticals Ltd.
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