BERICORT

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Deflazacort

COMPOSITION

Each Tablet of **BERICORT** contains : Deflazacort 6 mg

INDICATIONS

A wide range of conditions 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 AND ADMINISTRATION:

Doses of **BERICORT** vary widely in different diseases and different patients. In more serious and life-threatening conditions, high doses of deflazacort may need to be given. When deflazacort is used long term in relatively benign chronic diseases, the maintenance dose should be kept as low as possible. Dosage may need to be increased during periods of stress or in exacerbation of illness.

The dosage should be individually titrated according to diagnosis, severity of disease and patient response and tolerance. The lowest dose that will produce an acceptable response should be used.

Adults

For acute disorders, up to 120 mg/day **BERICORT** may need to be given initially. Maintenance doses in most conditions are within the range 3 - 18 mg/day.

The following regimens are for guidance only.

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.

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 deflazacort on alternate days.

Deflazacort withdrawal

In patients who have received more than physiological doses of systemic corticosteroids (approximately 9mg 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. Clinical assessment of disease activity may be needed during withdrawal. If the disease is unlikely to relapse on withdrawal of systemic corticosteroids but there is uncertainty about HPA suppression, the dose of systemic corticosteroids may be reduced rapidly to physiological doses. Once a daily dose equivalent to 9mg deflazacort is reached, dose reduction should be slower to allow the HPA-axis to recover.

Abrupt withdrawal of systemic corticosteroid treatment, which has continued up to 3 weeks, is appropriate if it is considered that the disease is unlikely to relapse. Abrupt withdrawal of doses up to 48 mg daily of deflazacort or equivalent for 3 weeks is unlikely to lead to clinically relevant HPA-axis suppression, in the majority of patients. In the following patient groups, gradual withdrawal of systemic corticosteroid therapy should be *considered* even after courses lasting 3 weeks or less:

- Patients who have had repeated courses of systemic corticosteroids, particularly if taken for greater than 3 weeks.
- When a short course has been prescribed within one year of cessation of long-term therapy (months or years).
- Patients who may have reasons for adrenocortical insufficiency other than exogenous corticosteroid therapy.
- Patients receiving doses of systemic corticosteroid greater than 48 mg daily of deflazacort (or equivalent),
- Patients repeatedly taking doses in the evening.

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

STORAGE AND HANDLING INSTRUCTIONS
Store in the original package.
Do not store above 25ºC.

PACKAGING INFORMATION
BERICORT .....Alu-Alu Pack of 10 tablets