Brand: Delicort-6™

Generic Name: Deflazacort
Dosage Form: Oral Tablet

Strength of Delicort-6™: Deflazacort 6 mg

Mechanism of Action (MOA) of Delicort-6™

1. Anti-inflammatory Action:

- Daflazocort in Delicort-6™ works by binding to glucocorticoid receptors (GRs) present in various tissues. Once bound, the glucocorticoid receptor-ligand complex translocates into the cell nucleus and regulates gene expression in inflammation.
- Delicort-6™ inhibits the production of pro-inflammatory cytokines and other mediators, such as prostaglandins and leukotrienes, by suppressing the activity of phospholipase A2 (the enzyme that generates arachidonic acid, a precursor to pro-inflammatory mediators).
- Delicort-6[™] also stabilizes cell membranes, reducing the release of inflammatory mediators.

2. Immunosuppressive Action:

- Daflazocort in Delicort-6[™] suppresses immune system activity by decreasing the function of immune cells like T lymphocytes and macrophages.
- Delicort-6[™] reduces the proliferation of immune cells and the production of antibodies, which is useful in controlling autoimmune conditions or diseases where the immune system is hyperactive.

3. Anti-allergic Effects:

 By decreasing the release of histamine and other mediators from mast cells, Daflazocort in Delicort-6™ helps reduce allergic reactions and inflammation associated with allergies.

4. Metabolic Effects:

O As a corticosteroid, Delicort-6™ also has metabolic effects, such as promoting gluconeogenesis (the formation of glucose from non-carbohydrate sources) and protein catabolism (breaking down proteins), which can lead to fluid retention, increased blood glucose, and muscle wasting with prolonged use.

5. 9α-Fluorination Advantage:

The fluorine atom at the 9α-position in Daflazocort in Delicort-6™ makes it less likely to cause sodium retention (which is often a problem with other corticosteroids) and may result in a lower incidence of certain side effects, such as hypertension and oedema.

Clinical Use:

 Daflazocort in Delicort-6™ is used in conditions where corticosteroids are indicated, such as autoimmune diseases, allergic conditions, inflammatory diseases, and in some cases, muscular dystrophies (e.g., Duchenne muscular dystrophy), due to its favourable side effect profile compared to other corticosteroids like prednisolone.

In summary, Daflazocort in Delicort-6™ works by suppressing inflammation and modulating immune responses through glucocorticoid receptor activation while offering a more favourable side effect profile, particularly in terms of sodium retention and metabolic effects.

Indications:

Deflazacort in Delicort-6™ is used for the treatment of:

- 1. Inflammatory conditions: Including rheumatoid arthritis, systemic lupus erythematosus, and other inflammatory diseases.
- 2. Autoimmune conditions: Such as polymyositis, dermatomyositis, and other immune-mediated diseases.
- 3. Allergic reactions: Including severe asthma, allergic rhinitis, and urticaria.
- 4. Treatment of Duchenne muscular dystrophy (DMD): In pediatric patients.
- 5. Other conditions: Chronic inflammatory diseases and conditions requiring immunosuppression.

Dosage and Administration: Delicort-6™

- Adults: The usual starting dose for inflammatory or autoimmune conditions ranges from 0.1 to 0.3 mg per kg of body weight per day, administered orally.
 Specific dosages depend on the condition being treated.
- Pediatric patients: For Duchenne muscular dystrophy, the recommended dose is typically 0.9 mg/kg per day.
- Administration: Take the tablet orally with or without food. If gastrointestinal discomfort occurs, it may help to take it with food.

Contraindications:

Deflazacort in Delicort-6™ should not be used under the following conditions:

- Hypersensitivity to deflazacort or any of its components.
- Active or untreated infections (such as fungal, bacterial, or viral infections).
- Live vaccines should not be administered to patients on deflazacort due to their immunosuppressive effect.

Warnings and Precautions:

- Infections: Deflazacort can suppress the immune system, increasing the risk of infections.
- Osteoporosis: Long-term use of corticosteroids can lead to bone thinning and fractures.
- Hypertension: Monitor blood pressure as corticosteroids can cause fluid retention and hypertension.
- Hyperglycemia: Can induce diabetes or worsen preexisting diabetes. Regular blood glucose monitoring is advised.
- Cataracts and Glaucoma: Long-term use can lead to eye problems, including cataracts and glaucoma.
- Peptic Ulcers: Use with caution in patients with a history of peptic ulcers.
- Adrenal suppression: Gradual tapering of the dose is required to prevent adrenal insufficiency.

Side Effects:

Common side effects include:

- Weight gain
- Fluid retention
- Elevated blood pressure
- Hyperglycaemia
- Increased appetite
- Mood changes (irritability, depression)
- Insomnia
- Increased risk of infections
- Gastric ulcers or indigestion

Drug Interactions:

- Other corticosteroids: Use of other corticosteroids can increase the risk of side effects.
- Antidiabetic drugs: May need dose adjustments due to the potential increase in blood glucose levels.
- Anticoagulants: May require monitoring as deflazacort can affect coagulation.
- Live vaccines: Avoid concurrent administration of live vaccines.

Pregnancy and Lactation:

- Pregnancy Category C: Deflazacort should be used during pregnancy only if the potential benefit justifies the risk to the foetus. It may be associated with fetal harm, particularly in the first trimester.
- Lactation: Excretion in breast milk is unknown, and the drug should be used with caution during breastfeeding.

Overdose:

Signs of overdose include symptoms of Cushing's syndrome (moon face, hyperglycemia, and hypertension). Seek medical attention immediately if an overdose is suspected. Treatment typically involves supportive care.

Storage:

- Store at room temperature (20°C to 25°C).
- Protect from moisture and light.

Special Considerations:

- Gradual tapering is important when discontinuing deflazacort to prevent withdrawal symptoms and adrenal insufficiency.
- Regular monitoring by a healthcare provider is recommended, particularly for long-term therapy (e.g., blood pressure, blood sugar levels, and bone density).

Packaging:

- Each Alu-Alu strip Delicort-6™ contains 10 tablets.
- Each box of Delicort-6™ contains 10 strips.

• **Note**: This summary provides general prescribing information.