CELABET Tablets

COMPOSITION
Each film coated tablet contains:
Betamethasone USP …… 0.25mg
Dexchlorpheniramine Maleate USP …… 2mg
Excipients ……. Q.S
Colour: Titanium Dioxide

USES
Celabet are recommended in the treatment of difficult cases of respiratory, dermatologic and ocular allergies, as well as ocular inflammatory disorders, where adjunctive systemic corticosteroid therapy is indicated.

HOW IT WORKS
Betamethasone: Betamethasone is a glucocorticoid receptor agonist. This leads to changes in genetic expression once this complex binds to the GRE. The antiinflammatory actions of corticosteroids are thought to involve lipocortins, phospholipase A2 inhibitory proteins which, through inhibition arachidonic acid, control the biosynthesis of prostaglandins and leukotrienes. The immune system is suppressed by corticosteroids due to a decrease in the function of the lymphatic system, a reduction in immunoglobulin and complement concentrations, the precipitation of lymphocytopenia, and interference with antigen-antibody binding. Betamethasone binds to plasma transcortin, and it becomes active when it is not bound to transcortin.
Dexchlorpheniramine: Competes with histamine for H1-receptor sites on effector cells in the gastrointestinal tract, blood vessels, and respiratory tract. Dexchlorpheniramine is the predominant active isomer of chlorpheniramine and is approximately twice as active as the racemic compound.

PHARMACOKINETICS
Betamethasone
Absorption: Absorbed readily after oral administration.
Distribution: Removed rapidly from the blood and distributed to muscle, liver, skin, intestines, and kidneys. Betamethasone is bound weakly to plasma proteins (transcortin and albumin). Only the unbound portion is active. Adrenocorticoids are distributed into breast milk and through the placental barrier.
Metabolism: Metabolized in the liver to inactive glucuronide and sulfate metabolites.
Excretion: Inactive metabolites and small amounts of unmetabolized drug are excreted by the kidneys. Insignificant quantities of drug also are excreted in feces. Biological half-life of drug is 36 to 54 hours.
Dexchlorphenamine:
Absorption: Slowly absorbed orally, bioavailability is about 25 to 50%.
Distribution: Widely distributed in a protein bound form.
Metabolism: Extensively metabolized in the body.
Excretion: Excreted through urine both as metabolites and parent drug.

ADVERSE REACTIONS
The following is a list of possible side-effects that may occur in medicines that contain Betamethasone and Dexchlorpheniramine Maleate. This is not a comprehensive list. These side-effects are possible, but do not always occur. Some of the side-effects may be rare but serious. Consult your doctor if you observe any of the following side-effects, especially if they do not go away.
- Skin atrophy
- Burning
- Itching
- Irritation
- Allergic contact dermatitis
- Hypertrichosis

DRUG INTERACTIONS
Betamethasone and Dexchlorpheniramine Tablets may interact with the following drugs and products:
- Alcohol
- Aminoglutethimide
- Amphotericin B
- Anticholinesterases
- Antidiabetics
- Antihistamines

DO NOT USE CELABET
If you are hypersensitive to Betamethasone and/or Dexchlorpheniramine.
If you have idiopathic thrombocytopenic purpura
If you are an infants
If you are a nursing mothers

PRAGNANCY AND LACTATION
The use of Betamethasone and Dexchlorpheniramine Tablets during pregnancy, in nursing mothers or in women of child-bearing age requires that the possible benefits of the drug be weighed against potential hazards to mother and fetus or infant. Infants born of mothers who have received substantial doses of corticosteroids during pregnancy should be observed carefully for signs of hypoadrenalism.

DOSE
Dosage should be individualized and adjusted according to the specific disease being treated, its severity and the response of the patient. As improvement occurs, the dosage should be reduced gradually to the minimum maintenance level and discontinued where possible. When symptoms of respiratory allergies are adequately controlled, slow withdrawal of the combination product and treatment with an antihistamine alone should be considered.
The recommended initial dosage of Betamethasone and Dexchlorpheniramine Tablets for adults and children over 12 years is 1 to 2 tablets four times daily, after meals and at bedtime. The dose is not to exceed 8 tablets per day. In younger children dosage should be adjusted according to the severity of the condition, and the response of the patient, rather than by age or body weight.
Children 6 to 12 Years: The recommended dosage is ½ tablet three times a day. If an additional daily dose is required, it should be taken preferably at bedtime. The dose is not to exceed 4 tablets a day.

OVERDOSE AND TREATMENT
Betamethasone and Dexchlorpheniramine Tablets is a combination product and, therefore, the potential toxicity of each of its components must be considered. Toxicity from a single excessive dose of Betamethasone and Dexchlorpheniramine Tablets results primarily from the dexchlorphenamine component. The estimated lethal dose of the antihistamine dexchlorphenamine maleate is 2.5 to 5.0 mg/kg.
Overdosage reactions with conventional (sedating) antihistamines may vary from central nervous system depression (sedation, apnea, diminished mental alertness, cardiovascular collapse) to stimulation (insomnia, hallucinations, tremors, convulsions) to death. Other signs and symptoms may include dizziness, tinnitus, ataxia, blurred vision and hypotension. In children, stimulation is dominant, as are atropine-like signs and symptoms (dry mouth; fixed, dilated pupils; flushing; fever and gastrointestinal symptoms). Hallucinations, incoordination, and convulsions of the tonic-clonic type may occur. In adults, a cycle consisting of depression with drowsiness and coma, and an excitement phase leading to convulsions followed by depression may occur.
A single excessive dose of betamethasone is not expected to produce acute symptoms. Except at the most extreme dosages, a few days of excessive glucocorticosteroid dosing is unlikely to produce harmful results except in patients betamethasone.
Treatment of Acute Overdosage: Immediately induce emesis (in a conscious patient) or administer gastric lavage. Dialysis has not been found helpful.
Treatment of the signs and symptoms of overdosage is symptomatic and supportive. Stimulants should not be used. Vasopressors may be used to treat hypotension. Convulsions are best treated with a short-acting depressant, such as thiopental. Maintain adequate fluid intake and monitor electrolytes in serum and urine, with particular attention to sodium and potassium balance. Treat electrolyte imbalance if necessary.

PRESENTATION
30 Tablets HDPE bottle pack, packed in printed and laminated carton.

STORAGE
Store in a dry place at a temperature below 30°c.

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