# DESLOCORT® syrup

**COMPOSITION**
**Active ingredients:**
Desloratadine.....1mg/mL.
Betamethasone.....0.05mg/mL.

**Excipients:**
Sorbitol, sodium benzoate, sodium citrate, citric acid monohydrate, disodium edetate, banana flavor, sugar, propylene glycol, methyl p-hydroxybenzoate, propyl p-hydroxybenzoate, purified water.

**PHARMACEUTICAL FORM**

Syrup, 60 and 90 mL bottle.

**PHARMACOTHERAPEUTIC GROUP**

Antihistamine - H1 receptor antagonist and corticosteroid (group III) in combination.

**PHARMACOLOGICAL ACTION**

DESLOCORT combines the anti-inflammatory and antiallergic effect of betamethasone and the non-sedative antihistamine action of desloratadine.
Desloratadine is a long acting histamine antagonist, with potent, selective peripheral H1-receptor antagonist activity.
Betamethasone is a synthetic, long acting, potent glucocorticoid with anti-inflammatory and immunosuppressive properties. It shows strong glucocorticoid and weak mineralocorticoid effect.

**INDICATIONS**

DESLOCORT is indicated for the treatment of severe allergic conditions which require coadministration of an antihistamine and a systemic corticosteroid: atopic dermatitis, angioedema, urticaria, seasonal and perennial allergic rhinitis, allergic reactions to food and medicines, allergic contact dermatitis and allergic processes involving the eye, such as allergic conjunctivitis.

**DOSAGE AND ADMINISTRATION**

DESLOCORT should not be administered to children under 2 years of age.
Children 2 to 5 years of age: 1.25 mL DESLOCORT syrup once daily.
Children 6 to 11 years of age: 2.5 mL DESLOCORT syrup once daily.
Adults and adolescents (12 years of age and over):
5 mL DESLOCORT syrup once daily.
Dosage may be adjusted according to each patient's needs. Treatment must be continued until a proper therapeutic response is observed.
In adult patients with liver or renal insufficiency, it is recommended to initiate treatment with half the recommended initial dose until the degree of therapeutic response is established.
Once the allergic symptoms suppressed, treatment should be discontinued gradually and treatment with an antihistamine alone should be considered if necessary.
If the drug is to be discontinued after long-term therapy, dosage should be decreased gradually.
Patients subject to unusual stress situations not related to the treated condition, such as surgery, infection or trauma, may require an increase in DESLOCORT dosage.
Use the measuring spoon provided in the pack to take the appropriate amount of syrup.

**PRECAUTIONS**

Patients who are on corticosteroids are more susceptible to infections than are healthy individuals. Corticosteroids may also mask some signs of current infection.
Prolonged use may produce posterior subcapsular cataracts, glaucoma with possible damage to the optic nerves, and may enhance the establishment of secondary ocular infections due to bacteria, fungi or viruses. Corticosteroids should be used cautiously in patients with ocular herpes simplex because of possible corneal perforation.
Average and large doses of corticosteroids can cause elevation of blood pressure, salt and water retention, and increased excretion of potassium. Dietary salt restriction and potassium supplementation may be necessary.
All corticosteroids increase calcium excretion.
While on corticosteroid therapy, patients should not be vaccinated against smallpox. Other immunization procedures should not be undertaken in patients who are on corticosteroids, especially on high doses, because of possible hazards of neurological complications and possible lack of antibody response.
Persons who are on corticosteroids should be warned to avoid exposure to chickenpox or measles, patients should also be advised that if they are exposed, medical advice should be sought without delay. Chickenpox and measles can have more serious or even fatal course in pediatric and adult patients on corticosteroids.
The lowest possible dose of corticosteroid should be used to control the condition under treatment. When reduction in dosage is possible, the reduction should be gradual.
There is an enhanced effect of corticosteroids on patients with hypothyroidism and in those with cirrhosis.
Psychic derangements may appear when corticosteroids are used. Existing emotional instability or psychotic tendencies may be aggravated by corticosteroids.
Corticosteroids should be used with caution in: nonspecific ulcerative colitis, if there is a probability of impending perforation, abscess or other pyogenic infection; diverticulitis; fresh intestinal anastomoses; active or latent peptic ulcer; renal insufficiency; hypertension; osteoporosis; and myasthenia gravis.
Growth and development of infants and children on prolonged corticosteroid therapy should be carefully observed, since corticosteroid administration can disturb growth rates and inhibit endogenous corticosteroid production in these patients. Corticosteroids may alter the motility and number of spermatozoa in some patients.

**CONTRAINDICATIONS**

DESLOCORT is contraindicated in patients with:
-Known hypersensitivity to desloratadine, loratadine, betamethasone, other corticosteroids or to any of the excipients.
-Systemic fungal infections.
-Active tuberculosis.

**INTERACTIONS**

Desloratadine:
There are no known interactions of desloratadine with other medicines.
Betamethasone:
-Potassium-depleting agents:
When corticosteroids are administered concomitantly with potassium-depleting agents (e.g., amphotericin B, diuretics), patients should be observed closely for development of hypokalemia.
-Cardiac glycosides:
Patients on cardiac glycosides may be at increased risk of arrhythmias due to hypokalemia.
-Anticoagulants:
Concurrent use of corticosteroids with coumarin-type anticoagulants may increase or decrease the anticoagulant effects, possibly requiring adjustment in dosage.
-Antidiabetics:
Because corticosteroids may increase blood glucose concentrations, dosage adjustments of antidiabetic agents may be required.
-Estrogens:
Estrogens may decrease the hepatic metabolism of certain corticosteroids, thereby increasing their effect.
-Non-steroidal anti-inflammatory drugs or alcohol:
Incidence and/or severity of gastrointestinal ulceration may increase.
Corticosteroids may decrease blood salicylate concentrations. Acetylsalicylic acid should be used cautiously in conjunction with corticosteroids in hypoprothrombinemia.
-Hepatic enzyme inducers (e.g., barbiturates: phenobarbital, primidone; phenytoin; carbamazepine; rifampicin; ephedrine):
Drugs which induce hepatic microsomal drug-metabolizing enzyme activity may enhance the metabolism of corticosteroids and require that the dosage of the corticosteroid be increased.
-Somatotropin:
Concomitant treatment with glucocorticoids may inhibit the response to somatotropin.

**Interactions with laboratory tests**

Glucocorticoids may produce false-negative results in the nitroblue tetrazolium test for systemic bacterial infection.
Discontinue administration of DESLOCORT approximately 48 hours before performing any type of skin tests, as antihistamines may prevent or diminish development of reactions which otherwise would be positive to dermal reactivity indicators.

**PREGNANCY AND LACTATION**

The safe use of DESLOCORT during pregnancy has not been established. DESLOCORT should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
DESLOCORT is excreted into breast milk, therefore the use of DESLOCORT is not recommended in breastfeeding women.

**EFFECTS ON ABILITY TO DRIVE AND USE MACHINES**

DESLOCORT may cause mood changes, visual disturbances or somnolence. Caution should be exercised in driving and operating machinery.

**SIDE EFFECTS**

Like all medicines, DESLOCORT can cause side effects, although not everybody gets them.
Desloratadine:
In clinical studies in most children and adults, the overall incidence of side effects was similar for the desloratadine and the placebo groups. However common side effects in children less than 2 years of age were diarrhea, fever and insomnia, while in adults and adolescents, fatigue, dry mouth and headache were reported in excess of placebo.
The following side effects were reported very rarely: hallucinations, dizziness, drowsinesss, insomnia, psychomotor hyperactivity, seizures, fast heartbeat, plapitations, abdominal pain, nausea, vomiting, upset stomach, diarrhea, elevations of liver enzymes, increased bilirubin, liver inflammation, muscle pain, severe allergic reactions (difficulty in breathing, wheezing, itching, hives and swelling), rash.
Betamethasone:
Side effects reported for betamethasone were similar to those reported to other corticosteroids and were related to dosage and treatment duration.
Fluid and electrolyte disturbances: sodium and fluid retention, potassium loss, hypokalemic alkalosis.
Cardiovascular: hypertension, congestive heart failure in susceptible patients.
Musculoskeletal: aseptic necrosis (tissue death) of femoral and humeral heads, loss of muscle mass, muscle weakness, osteoporosis, pathologic fracture of long bones, steroid myopathy, tendon rupture, vertebral compression fractures.
Gastrointestinal: peptic ulcer, digestive hemorrhage, pancreatitis, abdominal distention, increased appelite, ulcerative esophagitis, nausea.
Dermatologic: impaired wound healing, thin fragile skin, ecchymoses and petechiae, erythema, increased sweating, suppressed reactions to skin tests, allergic dermatitis, urticaria, angioneurotic edema.
Neurological: convulsions, increased intracranial pressure with papilledema (pseudotumor cerebri) usually following discontinuation of treatment, vertigo, headache.
Psychiatric: euphoria, mood swings, depression, personality changes, psychic disorders, insomnia, emotional instability.
Endocrine: menstrual irregularities, development of cushingoid state, hirsutism, suppression of growth in pediatric patients, secondary adrenocortical and pituitary unresponsiveness (particularly in times of stress, as in trauma, surgery, or illness), decreased carbohydrate and glucose tolerance, manifestations of latent diabetes mellitus, increased requirements for insulin or oral hypoglycemic agents in diabetes, weight gain, abnormal fat deposit, moon face (enlargement of face and forehead).
Ophtalmic: exophtalmous, glaucoma, increased intraocular pressure, posterior subcapsular cataracts.
Metabolic: negative nitrogen balance due to protein catabolism.
Other: anaphylactoid or hypersensitivity reactions and hypotensive reactions or reactions similar to shock conditions.

**OVERDOSAGE**

DESLOCORT is a combination product and therefore the potential toxicity of each of its components must be considered.
Desloratadine: No serious problems are expected with accidental overdose. Overdosage is limited to somnolence and increase in heart rate.
Betamethasone: Acute overdosage of corticosteroids, including betamethasone, is not expected to lead to a life-threatening situation.
However if you take more DESLOCORT syrup than you were told, tell your doctor or pharmacist immediately.
In the event of overdose, consider standard measures to remove unabsorbed active substance. Medical control is recommended specially emphasizing possible side effects of corticosteroids on metabolism, internal medium and digestive system.
Symptomatic and supportive treatment is recommended.

**PHARMACOKINETICS**

Desloratadine plasma concentrations can be detected within 30 minutes of administration. Desloratadine is well absorbed with maximum concentration achieved after approximately 3 hours; the terminal phase half-life is approximately 27 hours. Desloratadine is moderately bound (83-87%) to plasma proteins.
Betamethasone is well absorbed after oral administration. Betamethasone can already be detected in plasma 20 minutes after administration. Peak plasma concentrations are reached 2 hours after oral administration and they gradually decrease during the following 24 hours. Mean elimination half-life for betamethasone is ≥300 minutes and mean biological half-life is of about 36 to 54 hours. Betamethasone is metabolized in the liver.

**CONSERVATION**

Store below 30°C.
Keep out of the reach of children.

CHAPHA
PATIENT-CENTRIC SOLUTIONS

**Manufactured by**
**CHAOUL PHARMACEUTICALS**
**(CHA-PHA) S.A.L. - LEBANON**

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