Summary of Product Characteristics

1. Name of the medicinal product

1.1Product Name: CELESTINAC

1.2 Strength:

Each film coated tablets contains

Dexchlorpheniramine Maleate BP …….. 2 mg

Betamethasone BP ….. 0.25 mg

ColourErythrosine.

1.3 Pharmaceutical Dosage Form: Film-coated tablets

2. Qualitative and quantitative composition

Each film coated tablets contains

Dexchlorpheniramine Maleate BP …….. 2 mg

Betamethasone BP ….. 0.25 mg

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Film coated tablet

Pink coloured, round shaped, film coated tablet plain on one side breakline on other side

4. Clinical particulars

4.1 Therapeutic indications

Betamethasone and dexchlorpheniramine maleate are indicated for difficult cases of respiratory, ocular and dermatologic allergies, as well as ocular inflammatory disorders where adjunctive systemic corticosteroid therapy is indicated

4.2 Posology and method of administration

Dose of Celestinac depends on the patient's response to the drug and the severity of the illness.

In the case, the conditions are better; the dosage should be reduced little by little until it is reduced to a minimum.

After reaching the lowest dose, it should be suspended slowly.

For people older than 12 years, an initial dose of 1 or 2 tablets (1 or 2 tablespoons) is prescribed for four times a day.

It is best to take the dose after a filling meal or at bedtime.

Do not increase the dose of Celestinac s in more than eight tablets or 8 tablespoons in the case of Celestinac s syrup.

For children between 6 and 12 years, a dose of ½ tablet (1/2 tablespoon) should be administered three times a day. The dose should not exceed more than 4 tablets or 4 tablespoons in the case of syrup.

For children between 2 and 6 years old, a dose of ¼ or ½ tablespoon should be administered three times a day. The general dosage should not be more than two tablespoons. Summary of Celestinac dosage :

Age	Dose	Frequency	Maximum Dose
>12 years	1 or 2 tablets (1 or 2 tablespoons)	4 times/day	8 tablets or 8 tablespoons
6 - 12 years	½ tablet (1/2 tablespoon)	3 times/day	4 tablets or 4 tablespoons
2 - 6 years	¼ or ½ tablespoon	3 times/day	2 tablespoons

4.3 Contraindications

- Never use this drug in a patient who is having any fungal infections in the body.
- Should not be used in newborn and premature infants.
- Using Celestinac in patients who have shown hypersensitivity to Betamethasone or DexchlorphenamineMaleate or any chemical compounds similar to Celestinac should be avoided.
- Patients who are on therapy with Monoamine oxidase inhibitors (MAOIs)

4.4 Special warnings and precautions

for use If Celestinac contains

Betamathasone :

As it contains Betamethasone as an active ingredient, adjustments of dosages in both adults and children may be required with remission or exacerbation of the clinical condition. Also, we should consider each patient's individual response to therapy and exposure of the patient to psychological or physical stress such as injury, surgery or serious infection.

Betamethasone is a Corticosteroid, so we should monitor the patient for at least up to one year following the discontinuation of long-term or high-dose corticosteroid therapy.

Since complications of glucocorticoid therapy are dependent on duration and dosage of treatment, doctor should make the decision of risk or benefit for with each patient and their associated comorbidities.

Since high dose or long-term corticosteroid therapy is associated with many side effects like osteoporosis (fragile bones), hypertension (high blood pressure), diabetes etc. the lowest possible dose of corticosteroid should be used to control the condition under treatment. A gradual reduction of dosage is recommended.

When the drugs are used in patients who have other comorbidities like hypothyroidism and cirrhosis, adverse effects of corticosteroids are increased.

Patients who take corticosteroids should be cautious if it's used in patients with ocular herpes simplex because of possible risk of corneal perforation.

Psychological derangements also reported with corticosteroid therapy and those who already have emotional instability or psychotic tendencies may be aggravated by corticosteroid drugs like betamethasone/ Celestinac preparations.

These drugs should be used with caution conditions such as diverticulitis, fresh intestinal anastomoses, nonspecific ulcerative colitis, if there is a possible impending perforation, other pyogenic infection, abscess, or active or latent peptic ulcer disease, myasthenia gravis, osteoporosis, hypertension and renal insufficiency.

Since Corticosteroids are immunosuppressive agents, they may mask some signs of ongoing infection, and new infections may also appear during use. When corticosteroids are used, decreased resistance and inability to localize infection may occur.

Prolonged use of corticosteroid may lead to glaucoma with possible damage to the optic nerves, posterior subcapsular cataracts (mainly in children) and may increase the chance of secondary ocular infections due to fungi or viruses.

Elevation of blood pressure, retention of salt and water, and increased excretion of potassium which lead to hypokalemic complications may also occur with average and large doses of corticosteroids.

However, these side effects are less likely to occur when synthetic derivatives of corticosteroids are used except when used in large doses.

Supplementation of potassium and restriction of Dietary salt may be considered for these patients. All corticosteroids will increase excretion of calcium. So, it's advised to take calcium supplements or calcium rich foods to prevent complications that can occur with long term calcium deficiency.

Since corticosteroids have immunosuppressive actions, patients should never be vaccinated for small pox. Other immunization procedures also should never be undertaken in patients who receive treatments with corticosteroids like betamethasone, CELESTINAC etc., especially high doses, because of lack of antibody response and possible risk of neurological complications.

Patients who are on treatment with immunosuppressant doses of corticosteroids should be warned and they should avoid exposure to chicken pox or measles. If exposed, they should immediately obtain medical advice as it might end up in serious complications. This is particularly important in children, elderly patients and patients who are already on immunosuppressive state like diabetes mellitus.

Treatment with Corticosteroid is in active tuberculosis should be restricted to those patients with disseminated or fulminating tuberculosis in which the corticosteroid is used in conjunction with an appropriate antituberculous regimen.

If corticosteroids are used in patients with latent tuberculosis, close monitoring is necessary since reactivation of the disease may occur due to suppression of immune system. Patients should receive chemoprophylaxis during prolonged corticosteroid therapy.

Growth and development of children who receive corticosteroid therapy for a prolonged period should be assessed carefully, since administration of corticosteroid can disturb the growth rates and inhibit the production of endogenous corticosteroids in these patients.

Celestinac should not be used in newborn and premature infants.

Corticosteroid therapy may alter the motility and number of spermatozoa.

If Celestinac contains DexchlorpheniramineMaleate :
Celestinac products containing Betamethasone/Dexchlorphenamine Maleate should be used with caution in patients with pyloroduodenal obstruction, peptic ulcer disease, narrow angle glaucoma, prostatic hypertrophy or bladder neck obstruction, cardiovascular disease including hypertension, in those with increased intraocular pressure or hyperthyroidism.

Patients should be warned about involving in activities requiring mental alertness, such as driving vehicles or operating machines etc.

Dexchlorpheniramine is a first-generation histamine receptor antagonist which crosses the blood brain barrier and causes dizziness, sedation, and hypotension in patients over 60 years of age.

Use in Pregnancy: US FDA PREGNANCY RISK FACTOR C.
Corticosteroids have been shown to be teratogenic in many species when given in doses equivalent to the human dose. Animal studies in which corticosteroids have been given to pregnant mice, rats, and rabbits have yielded an increased incidence of cleft palate in the offspring. There are no adequate and well-controlled studies in pregnant women. Corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Infants born to mothers who have received corticosteroids during pregnancy should be carefully observed for signs of hypoadrenalism.

Use in Lactation: Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. Caution should be exercised when corticosteroids are administered to a nursing woman.

4.5 Interaction with other medicinal products and other forms of interaction Betamethasone:
Concurrent use of phenobarbital, phenytoin, rifampicin or ephedrine may enhance the metabolism of betamethasone, reducing its therapeutic effects.
Patients receiving estrogen should be observed for excessive corticosteroid effects. Concurrent use with potassium-depleting diuretics may enhance hypokalemia. Concurrent use with cardiac glycosides may enhance the possibility of arrhythmias or digitalis toxicity associated with hypokalemia. Betamethasone may enhance the potassium depletion caused by amphotericin B. Concurrent use with coumarin-type anticoagulants may increase or decrease the anticoagulant effects, possibly requiring adjustment in dosage.

Combined effects of non-corticosteroid anti-inflammatory drugs or alcohol with betamethasone may result in an increased occurrence or increased severity of gastrointestinal ulceration.

Dexchlorpheniramine maleate:
MAO inhibitors prolong and intensify the effects of chlorpheniramine; severe hypotension may occur. Concomitant use with alcohol, tricyclic antidepressants, barbiturates or other CNS depressants may potentiate the sedative effect of dexchlorpheniramine. The action of oral anticoagulants may be inhibited by dexchlorpheniramine.

4.6 Fertility, pregnancy and lactation
Use in Pregnancy & Lactation
US FDA PREGNANCY RISK FACTOR C. Corticosteroids have been shown to be teratogenic in many species when given in doses equivalent to the human dose. Animal studies in which corticosteroids have been given to pregnant mice, rats, and rabbits have yielded an increased incidence of cleft palate in the offspring. There are no adequate and well-controlled studies in pregnant women. Corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Infants born to mothers who have received corticosteroids during pregnancy should be carefully observed for signs of hypoadrenalism.
Use in Lactation: Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. Caution should be exercised when corticosteroids are administered to a nursing woman.

4.7 Effects on ability to drive and use machines
Not Available

4.8 Undesirable effects
- Nausea and vomiting are common side effects.
- Increased sweating
- It can produce a sedative effect in which a person is always sleepy or drowsy.
- In some people, an alteration in electrolyte and fluid balance is also seen.
- Muscle problems such as loss of muscle mass, weakness of muscle and rupture of the tendon are common.
- Sometimes depression, mood swings and some other psychological problems are also seen in Celestinac users.
- In cases of women, menstrual irregularity is also common
- Some people also complain of vertigo and headache.
- There are also complains distension of the abdomen.
- There are also cases of Peptic ulcer, constipation and irritable bowel syndrome can occur.
- Delayed wound healing is also seen.

- Skin discoloration, thinning of the skin are some of the common complains of Celestinac.

Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Reporting System (PvERS)
https://pv.pharmacyboardkenya.org

4.9 Overdose

Celestinac is a combination of Betamethasone/Dexchlorphenamine Maleate. So both components are responsible for the potential toxicities.

Overdosage reactions with Dexchlorphenamine Maleate may vary from depression of central nervous system such as sedation, respiratory depression, reduced mental alertness, cardiovascular collapse and stimulation of central nervous system such as insomnia, hallucinations, tremors, convulsions to death.

Other signs and symptoms of DexchlorphenamineMaleateoverdosage include may include tinnitus, dizziness, ataxia, blurred vision and hypotension. In adults, it causes depression with drowsiness and coma, and an excitement phase leading to convulsions followed by depression may occur. In children, stimulation if central nervous system is dominant where it causes atropine-like signs andsymptoms such as dry mouth, fixed dilated pupils,flushing, fever and gastrointestinal symptoms. Hallucinations, incoordination, and convulsions may also occur with Dexchlorphenamine Maleate toxicity. In adults, it causes depression with drowsiness and coma, and an excitement phase may lead to convulsions followed by depression may occur.

Single toxic dosage of betamethasone is not expected to cause acute problems. However, at most extreme dosages, signs and symptoms of corticosteroid toxicity is seen.

Treatment of Acute Overdosage

If the patient is conscious, immediately induce emesis. Gastric lavage may also be done. Dialysis is not shown to be helpful in Celestinac toxicity.
Stimulants should be avoided. Treatment of the signs and symptoms of overdosage is symptomatic and supportive. If the patient is hypotensive, vasopressors can be used. Convulsions are best treated with a short-acting depressant, such as thiopental.

Fluida maintenance should be perfectly done and electrolytes should be monitored in serum and urine, with particular attention to potassium and sodium balance. If there is electrolyte imbalance, treat immediately.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Betamethasone -ATC code S02BA Corticosteroids
Dexchlorpheniramine ATC code R06AB52 -, combinations; Belongs to the class of substituted alkylamines used as systemic antihistamines.

5.2 Pharmacokinetic properties

Betamethasone is rapidly absorbed from the gastro-intestinal tract upon oral administration and rapidly distributed to all body tissues. It also crosses the placenta and distributed in small amounts to breast milk.
Dexchlorpheniramine maleate is absorbed relatively slowly from the gastro-intestinal tract, peak plasma concentrations occurring about 2.5 to 6 hours after oral doses. Bioavailability is low, values of 25 to 50% having been reported.
Dexchlorpheniramine appears to undergo considerable first-pass metabolism. About 70% of dexchlorpheniramine in the circulation is bound to plasma proteins. Dexchlorpheniramine is widely distributed in the body, and enters the CNS.

5.3 Preclinical safety data

Not Available

6. Pharmaceutical particulars

6.1 List of excipients

Maize Starch
Lactose
Microcrystalline Cellulose
Maize Starch
Purified Talc
Magnesium Stearate
Cross Carmellose Sodium
Isopropyl Alcohol*
Methylene Dichloride*
Erythrosine

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 Months

6.4 Special precautions for storage
Store below 30°C. Keep the medicine out of reach of children.

6.5 Nature and contents of container
Tube pack

Pack Size: The tube contains a pack of 30 tablets inside a polyethylene bag, along with a silica gel bag. 1 Tube is packed in one carton box along with a packing leaflet. Such 1 Tube is packed in one carton box along with a packing leaflet.

6.6 Special precautions for disposal and other handling

None.

7. Marketing authorization holder and manufacturing site addresses Marketing authorization Warehouse pharmaceuticals
P.o Box 1120-00100
GPO, Nairobi
Email: warehousepharmaceuticals@gmail.com

MANUFACTURING SITE
MARS REMEDIES PVT LTD
635 G.I.D.C Estate Waghodia, Dist. Vadodara Gujarat (India)

8. Marketing authorization number

H2025/CTD12072/26679

9. Date of first registration
Oct 27 2025