

Crisaborole INN

Composition

Crisa 2% ointment: Each gram ointment contains Crisaborole INN 20 mg.

Pharmacology

Crisa (Crisaborole) is a phosphodiesterase 4 (PDE-4) inhibitor. PDE-4 inhibition results in increased intracellular cyclic adenosine monophosphate (cAMP) levels. While the specific mechanism by which Crisaborole exerts its therapeutic action is not well defined, Crisaborole reduces the production of some inflammatory cytokines implicated in the pathophysiology of Atopic Dermatitis.

Indication

Crisa (Crisaborole) ointment is used to treat mild to moderate Atopic Dermatitis in patients 2 years of age and older.

Dosage and Administration

Route of administration : External

Apply a thin layer of Crisa ointment twice daily to affected areas.

Crisaborole is for topical use only and not for ophthalmic, oral, or intravaginal use.

Contraindications

Crisaborole is contraindicated in patients with known hypersensitivity to Crisaborole or any component of the formulation.

Warning & Precautions

Hypersensitivity reactions including contact Urticaria, have occurred in patients treated with Crisaborole. Hypersensitivity should be suspected in the event of severe pruritus, swelling and erythema at the application site or at a distant site. If signs and symptoms of hypersensitivity occur, discontinue Crisaborole immediately and initiate appropriate therapy.

Side-Effects

Common side effects: Application site pain such as burning or stinging.

Rare side effects: Crisaborole may cause allergic reactions at or near the application site. These can be serious and may include hives, itching, swelling, and redness.

Use in Pregnancy & Lactation

There is no available data in pregnant women to inform the drug-associated risk for major birth defects and miscarriage.

There is no information available on the presence of Crisaborole in human milk, the effects of the drug on the breastfed infant, or the effects of the drug on milk production after topical application of Crisaborole to women who are breastfeeding.

Crisaborole is systemically absorbed.

Use in Children & Adolescents

The safety and effectiveness of Crisaborole have been established in pediatric patients age 3 months and older for topical treatment of mild to moderate Atopic Dermatitis.

Drug Interactions

In vitro studies using human liver microsomes indicated that under the conditions of clinical use, Crisaborole and metabolite-1 are not expected to inhibit cytochrome P450 (CYP) 1A2, 2B6, 2C8, 2C9, 2C19, 2D6, and 3A4.

In vitro human liver microsomes studies for metabolite-2 showed that Crisaborole did not inhibit activities of CYP2C19, 2D6, and 3A4.

Overdose

Crisaborole is not for oral use. If oral ingestion occurs, medical advice should be sought.

Storage

Store below 30° C temperature & dry place, protected from light.

Keep all medicines out of reach of children.

Packing

Crisa 2% Ointment: Each pack contains a laminated tube of 10 g ointment of Crisaborole INN 2% with an insert.

* Further information is available on request



Manufactured by:

The ACME Laboratories Ltd.
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