

Prescribing Information/Insert

Betnovate-CL™

Clotrimazole 1% and Betamethasone Valerate 0.1% Ointment

FOR TOPICAL USE ONLY, NOT FOR OPHTHALMIC, ORAL, OR INTRAVAGINAL USE AND NOT RECOMMENDED FOR DIAPER DERMATITIS

QUALITATIVE AND QUANTITATIVE COMPOSITION

Betnovate CL ointment contains combinations of clotrimazole, a synthetic antifungal agent, and betamethasone valerate, a synthetic corticosteroid, for dermatologic use.

Each gram of Betnovate-CL contains 10 mg clotrimazole and 0.122 mg betamethasone valerate (equivalent to 1.0 mg betamethasone).

INDICATIONS AND USAGE

Short-term topical treatment of tinea infections due to *Trichophyton rubrum*; *T. mentagrophytes*; *Epidermophyton floccosum* and *Microsporum canis*; candidiasis due to *Candida albicans*.

POSODOLOGY AND METHOD OF ADMINISTRATION

Posology

Adults and children over the age of 12 years.

Paediatric population

Betnovate-CL Ointment is not recommended for children under the age of twelve years.

Method of administration

Topical administration twice daily for two weeks (tinea cruris, tinea corporis and candidiasis) or for four weeks (tinea pedis).

CONTRAINDICATIONS

Betnovate-CL is contraindicated in those patients with a history of sensitivity to any of its components or to other corticosteroids or imidazoles.

If irritation or sensitization develops with the use of Betnovate-CL Ointment, treatment should be discontinued and appropriate therapy instituted.

Betnovate-CL Ointment is contraindicated in facial rosacea, acne vulgaris, perioral dermatitis, napkin eruptions and bacterial or viral infections.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Local and systemic toxicity is common especially following long continued use on large areas of damaged skin and in flexures. If used on the face, courses should be limited to 5 days.

Paediatric population

- Long term continuous therapy should be avoided in all children irrespective of age. Betnovate-CL Ointment should not be used with adhesive dressing.
- The safety and effectiveness of Betnovate-CL Ointment has not been established in children below the age of 12.
- If used on children, courses should be limited to 5 days.

Betnovate-CL OINTMENT SHOULD NOT BE USED WITH OCCLUSIVE DRESSING.

Topical corticosteroids may be hazardous in psoriasis for a number of reasons including rebound relapses following the development of tolerance, risk of generalised pustular psoriasis and local and systemic toxicity due to impaired barrier function of the skin.

Any of the side effects that are reported following systemic use of corticosteroids, including adrenal suppression, manifestation of Cushing's syndrome, hyperglycemia, and glycosuria may also occur with topical steroids, especially in infants and children.

Hypothalamic-pituitary adrenal axis suppression, Cushing's syndrome and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestation of adrenal suppression in children includes linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestation of intracranial hypertension includes bulging fontanelles, headaches, and bilateral papilloedema.

Betnovate-CL Ointment is not intended for ophthalmic use.

Visual disturbance may be reported with systemic and topical (including, intranasal, inhaled and intraocular) corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes of visual disturbances which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

There are no known interactions.

FERTILITY, PREGNANCY AND LACTATION

Pregnancy

There is inadequate evidence of safety in pregnancy. Clotrimazole has shown no teratogenic effect in animals but is foetotoxic at high oral doses.

Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intrauterine growth retardation. There may therefore be a very small risk of such effects in human foetus. Hence Betnovate-CL Ointment should only be used in pregnancy if the benefit justifies the potential risk to the foetus and such use should not be extensive i.e. in large amounts or for long periods.

Breastfeeding

It is not known whether the components of Betnovate-C are excreted in human milk and therefore caution should be exercised when treating nursing mothers.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Betnovate-CL Ointment has no influence on the ability to drive and use machines.

UNDESIRABLE EFFECTS

Adverse reactions reported for Betnovate-CL include: burning and stinging, maculopapular rash, oedema, paraesthesia and secondary infection.

Reported reactions to clotrimazole include erythema, stinging, blistering, peeling, oedema, pruritus, urticaria and general irritation of the skin.

Reactions to betamethasone valerate include: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, blurred vision, hyperpigmentation, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae miliaria, capillary fragility (ecchymoses) and sensitization.

In children receiving topical corticosteroids, Hypothalamic-pituitary-adrenal (HPA) axis suppression (HPA) axis suppression, Cushing's syndrome and intracranial hypertension have been reported.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via email at: bd.adverse-event@gsk.com.

OVERDOSE

Acute overdosage with topical application of Betnovate-CL Ointment is unlikely and would not be expected to lead to a life threatening situation; however topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects.

Toxic effects are unlikely to occur following accidental ingestion of Betnovate-CL Ointment. Signs of toxicology appearing after such accidental ingestion should be treated symptomatically.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Betnovate-CL Ointment contains the valerate ester of betamethasone, a glucocorticoid exhibiting the general properties of corticosteroids, and clotrimazole which is an imidazole antifungal agent.

Topical corticosteroids are effective in the treatment of a range of dermatoses because of their anti-inflammatory antipruritic and vasoconstrictive actions.

Clotrimazole is a broad-spectrum antifungal agent with activity against *Trichomonas*, *Staphylococci* and *Bacteroides*.

Pharmacokinetic properties

Betnovate-CL is intended for treatment of skin conditions and is applied topically. Thus there are minimal pharmacokinetic aspects related to bioavailability at the site of action.

Clotrimazole penetrates the epidermis after topical administration but there is little, if any, systemic absorption.

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including vehicle, integrity of skin and use of occlusion.

Systemically absorbed topical corticosteroids are bound to plasma proteins metabolised in the liver and excreted by the kidneys. Some corticosteroids and their metabolites are also excreted in the bile.

Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of this SmPC.

EXCIPIENTS

Liquid Paraffin/ Mineral Oil, White Soft Paraffin (Silkolene 394)/ (Rajell-UP12AD3)

INCOMPATIBILITIES

Not applicable.

SHELF LIFE

24 months.

SPECIAL PRECAUTIONS FOR STORAGE

Do not store above 30° C.

NATURE AND CONTENTS OF CONTAINER

Prescribing Information/Insert

Betnovate-CL is supplied in 10-gram aluminum tube.

SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING

No special requirements for disposal.

“Keep all medicine out of the reach of children”

MANUFACTURED BY:

GlaxoSmithKline Bangladesh Limited

Fouzderhat Industrial Area, Chittagong



Ref:

<https://www.medicines.org.uk/emc/medicine/31451>

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