

DATA SHEET

BETNOVATE™-C CREAM and OINTMENT

Betamethasone Valerate 0.1% w/w and Clioquinol 3% w/w

Qualitative and quantitative composition

The BETNOVATE-C skin preparation contains betamethasone 0.1% w/w (as betamethasone-17 valerate, the valerate ester) and clioquinol 3% w/w.

BETNOVATE-C Cream is a smooth, straw-coloured water-miscible cream.

BETNOVATE-C Ointment is a white or pale straw-coloured paraffin-based ointment.

Pharmaceutical form

Cream and Ointment.

Clinical particulars

Therapeutic Indications

BETNOVATE-C preparations are indicated for the treatment of the following conditions where secondary bacterial and/or fungal infection is present, suspected or likely to occur:-

Eczema including atopic, infantile and discoid eczemas.

Prurigo nodularis.

Psoriasis (excluding widespread plaque psoriasis).

Neurodermatoses including lichen simplex, lichen planus.

Seborrhoeic dermatitis.

Contact sensitivity reactions.

Insect bite reactions.

Prickly heat.

Anal and genital intertrigo.

Otitis externa.

Posology and Method of Administration

A small quantity should be applied gently to the affected area two or three times daily until improvement occurs. It may then be possible to maintain improvement by applying once a day or even less often. BETNOVATE-C cream is often appropriate for moist or weeping surfaces, and BETNOVATE-C ointment for dry, lichenified or scaly lesions, but this is not invariably so.

In the more resistant lesions, such as the thickened plaques of psoriasis on elbows and knees, the effect of BETNOVATE-C can be enhanced, if necessary, by occluding the treatment area with polythene film. Overnight occlusion only is usually adequate to bring about a satisfactory response in such lesions, thereafter improvement can usually be maintained by regular application without occlusion.

Contraindications

Where there is coexisting infection, otherwise concurrent antimicrobial therapy required.

Rosacea.

Acne vulgaris.

Peri-oral dermatitis.

Perianal or genital pruritus.

Primary cutaneous viral infections (e.g., herpes simplex, chickenpox).

Hypersensitivity to any component of the preparation or to iodine.

Use of BETNOVATE-C skin preparations is not indicated in the treatment of primary infected skin lesions caused by infection with fungi or bacteria; primary or secondary infections due to yeast; dermatoses in children under one year of age, including dermatitis and napkin eruptions.

The use of dermal corticosteroids in the eye is contraindicated.

Special Warnings and Special Precautions for Use

Long-term continuous topical therapy should be avoided where possible, particularly in infants and children, as adrenal suppression can occur even without occlusion.

Systemic absorption and hypothalamic-pituitary axis suppression may occur. Use for longer than 4 weeks can cause atrophic striae, prolonged use on flexures and in intertriginous areas is undesirable.

The face, more than other areas of the body, may exhibit atrophic changes after prolonged treatment with potent topical corticosteroids. This must be borne in mind when treating such conditions as psoriasis, discoid lupus erythematosus and severe eczema.

If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye, as glaucoma might result.

Topical steroids may be hazardous in psoriasis for a number of reasons, including rebound relapses, development of tolerance, risk of generalised pustular psoriasis and development of local or systemic toxicity due to impaired barrier function of the skin. If used in psoriasis careful patient supervision is important.

If infection persists, systemic chemotherapy is required. Any spread of infection requires withdrawal of topical corticosteroid therapy.

Bacterial infection is encouraged by the warm, moist conditions induced by occlusive dressings, and the skin should be cleansed before a fresh dressing is applied.

BETNOVATE-C may stain hair, skin or fabric, and the application should be covered with a dressing to protect clothing.

Products which contain antimicrobial agents should not be diluted.

There is a theoretical risk of neurotoxicity from the topical application of clioquinol particularly when BETNOVATE-C is used for prolonged periods or under occlusion.

Interaction with Other Medicinal Products and Other Forms of Interaction

None reported.

Use During Pregnancy and Lactation

Topical administration of corticosteroids to pregnant animals should be limited because of possible teratogenic effects to foetal development. The relevance of this finding to human beings has not been established; however, topical steroids should not be used extensively in pregnancy, i.e., in large amounts or for prolonged periods.

Effects on Ability to Drive and Use Machines

BETNOVATE-C is not expected to have an effect.

Undesirable Effects

Adverse events are listed below by system organ class and frequency. Frequencies are defined as: very common ($\geq 1/10$), common ($\geq 1/100$ and $< 1/10$), uncommon ($\geq 1/1000$ and $< 1/100$), rare ($\geq 1/10,000$ and $< 1/1000$) and

very rare (<1/10,000) including isolated reports. Very common, common and uncommon events were generally determined from clinical trial data. The background rates in placebo and comparator groups were not taken into account when assigning frequency categories to adverse events derived from clinical trial data, since these rates were generally comparable to those in the active treatment group. Rare and very rare events were generally determined from spontaneous data. [1]

Immune system disorders

Very rare: Hypersensitivity.

If signs of hypersensitivity appear, application should stop immediately.

Endocrine disorders

Very rare: Features of hypercortisolism.

As with other corticosteroids, prolonged use of large amounts or treatment of extensive areas, can result in sufficient systemic absorption to produce the features of hypercortisolism. This effect is more likely to occur in infants and children, and if occlusive dressings are used. In infants, the napkin may act as an occlusive dressing.

Vascular disorders

Very rare: Dilatation of the superficial blood vessels.

Prolonged and intensive treatment with highly active corticosteroid preparations may cause dilatation of the superficial blood vessels, particularly when occlusive dressings are used or when skin folds are involved.

- Skin and subcutaneous tissue disorders [2]

Common: Local skin burning and pruritus.

Very rare: Thinning, striae, pigmentation changes, hypertrichosis, allergic contact dermatitis, pustular psoriasis, exacerbation of symptoms.

Prolonged and intensive treatment with highly active corticosteroid preparations may cause local atrophic changes in the skin such as thinning and striae, particularly when occlusive dressings are used or when skin folds are involved.

In very rare instances, treatment of psoriasis with corticosteroid (or its withdrawal) is thought to have provoked the pustular form of the disease.

Overdose

Acute overdosage is very unlikely to occur, however, in the case of chronic overdosage or misuse the features of hypercortisolism may appear and in this

situation topical steroids should be discontinued gradually under medical supervision because of the risk of adrenal insufficiency.

Pharmacological properties

Pharmacodynamic properties

Betamethasone valerate is an active topical corticosteroid which produces a rapid response in those inflammatory dermatoses that are normally responsive to topical corticosteroid therapy, and is often effective in the less responsive conditions such as psoriasis.

Clioquinol is an anti-infective agent which has both antibacterial and anticandidal activity.

Pharmacokinetic properties

The following data apply to BETNOVATE-C skin preparations.

As with other topical corticosteroids, sufficient betamethasone valerate may be absorbed to give systemic effects if applied under an occlusive dressing or when the skin is broken.

Pharmaceutical particulars

List of Excipients

BETNOVATE-C Cream

Chlorocresol
Cetomacrogol 1000
Cetostearyl Alcohol
White Soft Paraffin
Liquid Paraffin
Sodium Dihydrogen Phosphate Dihydrate
Phosphoric Acid
Sodium Hydroxide
Purified Water

BETNOVATE-C Ointment

Liquid paraffin
White soft paraffin

Incompatibilities

None reported.

Shelf Life

3 years.

Special Precautions for Storage

BETNOVATE-C Cream

Store below 30°C.

BETNOVATE-C Ointment

Store below 25°C.

Nature and Contents of Container

Collapsible aluminium tubes, internally coated with an epoxy resin based lacquer and closed with a wadless polypropylene cap.

BETNOVATE-C Cream and Ointment are supplied in 15g tubes.

Instructions for Use/Handling

No special instructions.

Medicines classification

Prescription Only Medicine

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