

Betnovate-C™ Cream and Ointment

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Betamethasone 17-valerate with clioquinol.

To the Medical and Pharmaceutical Professions.

Presentations

Not all presentations are registered in every country.

Betamethasone 0.1% w/w (as betamethasone-17 valerate) with clioquinol 3% w/w.

Indications

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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.
- Seborrhoeic dermatitis.
- Contact sensitivity reactions.
- Insect bite reactions.
- Anal and genital intertrigo.
- discoid lupus erythematosus.



Dosage and 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.

Children:

Courses should be limited to five days if possible. Occlusion should not be used. For topical application.

Contra-indications

Rosacea.

Acne vulgaris.

Perioral 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.

Precautions and Warnings

Long-term continuous topical therapy should be avoided where possible, particularly in infants and children, as adrenal suppression, with or without clinical features of Cushing's syndrome, can occur even without occlusion.

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.

Pregnancy and Lactation

Topical administration of corticosteroids to pregnant animals can cause abnormalities of fetal 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.

Adverse Reactions

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

There are reports of local skin burning, pruritus, pigmentation changes, hypertrichosis and allergic contact dermatitis with topical steroids.

As with other topical corticosteroids, prolonged use of large amounts, or treatment of extensive areas, can result in sufficient systemic absorption to produce the features of hypercortisolism. The 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.

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

The Betnovate preparations are usually well tolerated, but if signs of hypersensitivity appear, application should stop immediately.

Exacerbation of symptoms may occur.

Overdosage

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.

Pharmaceutical Precautions and Recommendations

Do not store above 30°C.

Shelf Life

3 years.

List of Excipients

Betnovate-C Cream

Chlorocresol
Cetomacrogol 1000
Cetostearyl Alcohol
White Soft Paraffin
Liquid Paraffin
Sodium Acid Phosphate
Phosphoric Acid
Sodium Hydroxide

Purified Water

Betnovate-C Ointment

Liquid paraffin
White soft paraffin

Nature and Contents of Container

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

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