SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Betamethasone valerate/Clioquinol 1 mg/30 mg/g Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 g of cream contains 1.22 mg of Betamethasone Valerate BP and 30 mg of Clioquinol BP.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Aqueous Cream

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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.

Betamethasone/Clioquinol skin 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 in children and adults, including atopic and discoid eczemas, prurigo nodularis; psoriasis (excluding widespread plaque psoriasis); neurodermatoses; seborrhoeic dermatitis; contact sensitivity reactions and discoid lupus erythematosus.

Betamethasone/Clioquinol skin preparations can also be used in the management of secondary infected insect bites and anal and genital intertrigo.

The cream is often appropriate for moist or weeping surfaces and the ointment for dry, lichenified or scaly lesions, but this is not invariably so.

4.2 Posology and method of administration

A small quantity of cream 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.

Children

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

For topical application.

4.3 Contraindications

Rosacea, acne vulgaris and perioral dermatitis. Primary cutaneous viral infections (e.g. herpes simplex, chickenpox). Hypersensitivity to any component of the preparation or to iodine.

Use of Betamethasone/Clioquinol skin preparations is not indicated in the treatment of primary infected skin lesions caused by infection with fungi (e.g. candidiasis, tinea); or bacteria (e.g. impetigo); primary or secondary infections due to yeast; perianal or genital pruritus dermatoses in children under 1 years of age, including dermatitis and napkin eruptions.

4.4 Special warnings and precautions for use

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. In this situation, topical steroids should be discontinued gradually under medical supervision because of the risk of adrenal insufficiency (see section 4.8 and section 4.9).

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

If used in childhood, or on the face, courses should be limited to five days and occlusion should not be used.

Topical corticosteroids 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.

Do not continue for more than 7 days in the absence of clinical improvement, since occult extension of infection may occur due to the masking effect of the steroid.

This medicinal product 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.

The least potent corticosteroid which will control the disease should be selected. These preparations do not contain lanolin or parabens.

There is a theoretical risk of neurotoxicity from the topical application of clioquinol, particularly when Betamethasone/Clioquinol skin preparations are used for prolonged periods or under occlusion.

Fire hazard in contact with dressings clothing and bedding
Instruct patients not to smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

4.5 Interaction with other medicinal products and other forms of interaction

None.

4.6 Fertility, pregnancy and lactation

There is inadequate evidence of safety in human pregnancy. 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 the human foetus.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

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.

As with other topical corticosteroids, prolonged use of large amounts or treatment of extensive areas can result in sufficient systemic absorption to produce suppression of the HPA axis and the clinical features of Cushing's syndrome (see section 4.4). These effects are 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 (see section 4.4).

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

Betamethasone/Clioquinol skin preparations are usually well tolerated, but if signs of hypersensitivity appear, application should be stopped immediately.

Exacerbation of symptoms may occur.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Acute overdosage is very unlikely to occur. However, in the case of chronic overdosage or misuse the features of Cushing's syndrome may appear and in this situation topical steroids should be discontinued gradually under medical supervision (see Section 4.4 Special Warnings and Precautions for use).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Betamethasone valerate is an active corticosteroid with topical anti-inflammatory activity.

Clioquinol is an anti-infective agent which has both anti-bacterial and anti-candidal activity.

5.2 Pharmacokinetic properties

The extent of percutaneous absorption of topical corticosteroid is determined by many factors including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings.

Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption. Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids.

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systematically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. Corticosteroids are metabolised primarily by the liver and are then excreted by the kidneys.

5.3 Preclinical safety data

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.2 Incompatibilities

None known.

6.3 Shelf life

36 Months.

6.4 Special precautions for storage

Store below 30°C

6.5 Nature and contents of container

15 gm and 30 gm collapsible aluminium tubes coated with an epoxy resin based lacquer with an aluminium membrane seal and a polyethylene cap.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special instructions.

7. MARKETING AUTHORISATION HOLDER

Chemidex Pharma Limited,
Trading as Essential Generics,
Chemidex House,
7 Egham Business Village,
Crabtree Road,
Egham, Surrey TW20 8RB,
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8 MARKETING AUTHORISATION NUMBER(S)

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