SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

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

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 gram of ointment contains 1.22 mg betamethasone valerate (equivalent to 1.0 mg betamethasone) and 30 mg clioquinol.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Ointment

A smooth yellow ointment.

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 ointment is often appropriate for dry, lichenified or scaly lesions, but this is not invariably so.

4.2 Posology and method of administration

Posology

A small quantity of ointment 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.

Paediatric population

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

Method of administration

For topical administration.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Use of Betamethasone/Clioquinol skin preparations is not indicated in the treatment of:

- Rosacea,
- Acne vulgaris
- Perioral dermatitis
- Primary cutaneous viral infections (e.g. herpes simplex, chickenpox)
- 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 2 years of age, including dermatitis and napkin eruptions.

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

Reversible hypothalamic-pituitary-adrenal (HPA) axis suppression

Manifestations of hypercortisolism (Cushing's syndrome) and reversible hypothalamic-pituitary-adrenal (HPA) axis suppression can occur in some individuals as a result of increased systemic absorption of topical corticosteroids. In this situation, topical steroids should be discontinued gradually under medical supervision because of the risk of adrenal insufficiency (see sections 4.8 and 4.9).

Application to the Face

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.

Application to the Eyelids

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

Visual disturbance

Visual disturbance may be reported with systemic and topical 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 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.

Chronic leg ulcers

Topical corticosteroids are sometimes used to treat the dermatitis around chronic leg ulcers. However, this use may be associated with a higher occurrence of local hypersensitivity reactions and an increased risk of local infection.

Paediatric population

In comparison with adults, children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic adverse effects. If used in childhood, or on the face, courses should be limited to five days and occlusion should not be used.

Use in Psoriasis

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.

Long term continuous or inappropriate use of topical steroids can result in the development of rebound flares after stopping treatment (topical steroid withdrawal syndrome). A severe form of rebound flare can develop which takes the form of a dermatitis with intense redness, stinging and burning that can spread beyond the initial treatment area. It is more likely to occur when delicate skin sites such as the face and flexures are treated. Should there be a reoccurrence of the condition within days to weeks after successful treatment a withdrawal reaction should be suspected. Reapplication should be with caution and specialist advise is recommended in these cases or other treatment options should be considered.

Infection

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.

Staining

This medicinal product may stain hair, skin or fabric, and the application should be covered with a dressing to protect clothing.

Dilution

Products which contain antimicrobial agents should not be diluted.

The least potent corticosteroid which will control the disease should be selected.

Neurotoxicity

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.

These preparations do not contain lanolin or parabens.

The label will state strong steroid.

4.5 Interaction with other medicinal products and other forms of interaction

Co-administered drugs that can inhibit CYP3A4 (e.g. ritonavir, itraconazole) have been shown to inhibit the metabolism of corticosteroids leading to increased systemic exposure. The extent to which this interaction is clinically relevant depends on the dose and route of administration of the corticosteroids and the potency of the CYP3A4 inhibitor

Theoretical concerns exist that oculotoxic effects of vigabatrin may be additive with cliquinol. Vigabatrin should not be used with clioquinol.

4.6 Fertility, pregnancy and lactation

Fertility

There are no data in humans to evaluate the effect of betamethasone valerate-clioquinol on fertility.

Pregnancy

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 fetus.

Breast-feeding

The safe use of Betamethasone/Clioquinol during lactation has not been established.

It is not known whether topical administration of corticosteroids could results in sufficient systemic absorption to produce detectable amounts in breast milk.

Administration of Betamethasone/Clioquinol during lactation should only be considered if the expected benefit to the mother outweighs the risk to the infant.

If used during lactation, Betamethasone/Clioquinol should not be applied to the breasts to avoid accidental ingestion by the infant.

4.7 Effects on ability to drive and use machines

Betamethasone/Clioquinol skin preparations has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Adverse reactions are listed below by MedDRA system organ class and frequency. Frequencies are defined as: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1000 to <1/100), rare (≥1/10,000 to <1/1000) and very rare (<1/10,000) including isolated reports.

Post-marketing data

Infections and Infestations

Very rare Opportunistic infection

Immune System Disorders

Very rare Local hypersensitivity

Endocrine Disorders

Very rare	Hypothalamic-pituitary-adrenal (HPA) axis suppression: Cushingoid features (e.g. moon face, central obesity), delayed weight gain/growth retardation in children, osteoporosis, glaucoma, hyperglycaemia/glucosuria, cataract, hypertension, increased weight/obesity, decreased endogenous cortisol levels, alopecia, trichorrhexis

Skin and Subcutaneous Tissue Disorders

Common	Pruritus, local skin burning/skin pain
Very rare	Allergic contact dermatitis/dermatitis, erythema, rash, urticaria, pustular psoriasis, skin thinning*/skin atrophy*, skin wrinkling*, skin dryness*, striae*, telangiectasias*, pigmentation changes, hypertrichosis, exacerbation of underlying symptoms *Skin features secondary to local and or systemic effects of hypothalamic-pituitary adrenal (HPA) axis suppression.

General Disorders and Administration Site Conditions

Very rare	Application site irritation/pain Eye disorders

Eye disorders

Not known	Vision, blurred (see also section 4.4)

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 Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Corticosteroids, potent, combinations with antibiotics, ATC code: D07CC01

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

Liquid paraffin

White soft paraffin

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

4 years.

6.4 Special precautions for storage

Store below 30°C.

6.5 Nature and contents of container

Collapsible aluminium tubes coated with an epoxy resin-based lacquer with an aluminium membrane seal and a polyethylene cap.

Pack sizes: 15 g and 30 g.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Chemidex Pharma Ltd,

Trading as Essential Generics,

8a Crabtree Road,

Egham, Surrey

TW20 8RN

8 MARKETING AUTHORISATION NUMBER(S)

PL 17736/0097

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

01/02/1993

10 DATE OF REVISION OF THE TEXT

16/10/2025