SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Betamethasone valerate/Neomycin sulphate 1 mg/5 mg/g Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 g of cream contains 1.22 mg of Betamethasone Valerate BP and 5 mg of Neomycin Sulphate BP.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Aqueous Cream

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Betamethasone/Neomycin skin preparations are indicated for the treatment of the following conditions where secondary bacterial infection is present, suspected, or likely to occur: eczema in adults and children (aged 2 years and over), including atopic and discoid eczemas; prurigo nodularis; psoriasis (excluding widespread plaque psoriasis); neurodermatoses including lichen simplex and lichen planus; seborrhoeic dermatitis; contact sensitivity reactions; insect bite reactions; and anal and genital intertrigo.

4.2 Posology and method of administration

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

In adults, in the more resistant lesions, such as the thickened plaques of psoriasis on elbows and knees, the effects of this medicinal product 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.

Treatment should not be continued for more than 7 days without medical supervision.

<u>Adults and children aged 2 years and over:</u>
A small quantity should be applied 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.

Betamethasone/Neomycin skin preparations are suitable for use in children (2 years and over) at the same dose as adults. When used in children, courses should be limited to 5 days, if possible.

A possibility of increased absorption exists in very young children, thus this medicinal product is not recommended for use in neonates and infants younger than 2 years of age (see section 4.3 and section 4.4).

Dosage in renal impairment:
Dosage should be reduced in patients with reduced renal function (see section 4.4).

Elderly:
Betamethasone/Neomycin skin preparations are suitable for use in the elderly. Caution should be exercised in cases where a decrease in renal function exists and significant systemic absorption of neomycin sulphate may occur (see section 4.4).

For topical administration.

4.3 Contraindications

- Rosacea.
- Acne vulgaris.
- Perioral dermatitis.
- Perianal and genital pruritus.
- Primary cutaneous viral infections (e.g. herpes simplex, chickenpox).
- Hypersensitivity to any component of the preparation.
- Use 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; or secondary infections due to *Pseudomonas* or *Proteus* species.
- Dermatoses in children under 2 years of age, including dermatitis and napkin eruptions. A possibility of increased absorption exists in very young children, thus this medicinal product is not recommended for use in neonates and infants (up to 2 years). In neonates and infants, absorption by immature skin may be enhanced, and renal function may be immature.
- Preparations containing neomycin should not be used for the treatment of otitis externa when the ear drum is perforated, because of the risk of ototoxicity.
- Due to the known ototoxic and nephrotoxic potential of neomycin sulphate, the use of Betamethasone/Neomycin skin preparations in large quantities or on large areas for prolonged periods of time is not recommended in circumstances where significant systemic absorption may occur.

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).

If infection persists, systemic chemotherapy is required.

Withdraw topical corticosteroid if there is a spread of infection.
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.

Avoid prolonged 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.

If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye, as glaucoma might result. If Betamethasone/Neomycin Cream does enter the eye, the affected eye should be bathed in copious amounts of water.

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.

Extended or recurrent application may increase the risk of contact sensitisation.

Extension of infection may occur due to the masking effect of the steroid.

Following significant systemic absorption, aminoglycosides such as neomycin can cause irreversible ototoxicity; and neomycin has nephrotoxic potential.

In renal impairment the plasma clearance of neomycin is reduced (see Dosage in renal impairment, section 4.2).

Products which contain antimicrobial agents should not be diluted.

4.5 Interaction with other medicinal products and other forms of interaction

Following significant systemic absorption, neomycin sulphate can intensify and prolong the respiratory depressant effects of neuromuscular blocking agents.

4.6 Fertility, pregnancy and lactation

There is little information to demonstrate the possible effect of topically applied neomycin in pregnancy and lactation. However, neomycin present in maternal blood can cross the placenta and may give rise to a theoretical risk of foetal toxicity, thus use of this medicinal product is not recommended in pregnancy or lactation.

4.7 Effects on ability to drive and use machines

None known

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/Neomycin 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).

Also, consideration should be given to significant systemic absorption of neomycin sulphate (see 4.4 Special Warnings and Precautions for Use). If this is suspected, use of the product should be stopped and the patient's general status, hearing acuity, renal and neuromuscular functions should be monitored.

Blood levels of neomycin sulphate should also be determined. Haemodialysis may reduce the serum level of neomycin sulphate.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Betamethasone valerate is an active 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.

Neomycin sulphate is a broad spectrum, bactericidal antibiotic effective against the majority of bacteria commonly associated with skin infections.

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

6.2 Incompatibilities

None known

6.3 Shelf life

36 Months.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

15 gm, 30 gm and 100 gm collapsible aluminium tubes internally coated with an epoxy resin based lacquer and closed with a wadless polypropylene cap.

6.6 Special precautions for disposal

Do not dilute

7. MARKETING AUTHORISATION HOLDER

Chemidex Pharma Limited,
Trading as Essential Generics,
Chemidex House,
7 Egham Business Village,
Crabtree Road,
Egham, Surrey TW20 8RB,
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 17736/0098

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

01/03/1993 / 21/12/2004

10 DATE OF REVISION OF THE TEXT

15/10/2015