SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Betamethasone Valerate 0.025% w/w Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One gram of cream contains 0.25 mg of betamethasone (0.025% w/w) as valerate.

Also contains 72 mg of cetostearyl alcohol and 1 mg of chlorocresol.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream

White to almost white cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Betamethasone Valerate preparations are indicated for the treatment of: eczema in children over 1 year elderly and adults; including atopic and discoid eczemas; prurigo nodularis; psoriasis (excluding widespread plaque psoriasis); neurodermatoses, including lichen simplex, lichen planus; seborrhoeic dermatitis; contact sensitivity reactions; discoid lupus erythematosus and they may be used as an adjunct to systemic steroid therapy in generalised erythroderma.

Betamethasone Valerate 0.025% preparations are indicated for maintenance treatment when control has been achieved with Betamethasone Valerate 0.1%.

In general, ointment preparations are particularly appropriate for dry, lichenified or scaly skin conditions whereas a cream preparation may be more suitable in the case of moist or weeping lesions.

4.2 Posology and method of administration

For topical use only.

If no improvement is seen after two to four weeks, the diagnosis should be reconsidered and specialist referral may be necessary.

This regimen should be combined with routine daily use of emollients.

Adults, adolescents and the elderly

A small quantity of Betamethasone Valerate Cream should be applied to the affected area one to three times daily or as directed by physician until improvement occurs. It may then be possible to maintain improvement by applying once a day, or even less often, or by using the appropriate ready diluted (1 in 4) preparation, Betamethasone Valerate 0.025% Cream.

In the more resistant lesions, such as the thickened plaques of psoriasis on elbows and knees, the effect of Betamethasone Valerate Cream 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.

Paediatric population

Betamethasone valerate is contraindicated in children under one year of age.

Children are more likely to develop local and systemic side effects of topical corticosteroids and, in general, require shorter courses and less potent agents than adults; Courses should be limited to five days. Occlusion should not be used.

Care should be taken when using betamethasone valerate to ensure the amount applied is the minimum that provides therapeutic benefit.

Elderly

Clinical studies have not identified differences in responses between the elderly and younger patients. The greater frequency of decreased hepatic or renal function in the

elderly may delay elimination if systemic absorption occurs. Therefore the minimum quantity should be used for the shortest duration to achieve the desired clinical benefit.

Renal / Hepatic Impairment

In case of systemic absorption (when application is over a large surface area for a prolonged period) metabolism and elimination may be delayed therefore increasing the risk of systemic toxicity. Therefore the minimum quantity should be used for the shortest duration to achieve the desired clinical benefit.

4.3 Contraindications

Rosacea, acne vulgaris, Pruritus without inflammation, perioral dermatitis and use in widespread plaque psoriasis. Primary cutaneous viral infections (e.g. herpes simplex, chickenpox). Hypersensitivity to any component of the preparation.

The use of Betamethasone Valerate skin preparations is not indicated in the treatment of primarily infected skin lesions caused by infections with fungi (e.g. candidiasis, tinea); or bacteria (e.g. impetigo); primary or secondary infections due to yeast; peri-anal and genital pruritus; dermatoses in children under 1 year 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 and reversible hypothalamic-pituitary-adrenal (HPA) axis, can occur even without occlusion. In this situation, topical steroids should be discontinued gradually under medical supervision by reducing the frequency of application, or by substituting a less potent corticosteroid because of the risk of adrenal insufficiency (see section 4.8 Undesirable Effects and Section 4.9 Overdose).

Risk factors for increased systemic effects are:

- Potency and formulation of topical steroid
- Duration of exposure
- Application to a large surface area
- Use on occluded areas of skin e.g. on intertriginous areas or under occlusive dressings (in infants the nappy may act as an occlusive dressing)
- Increasing hydration of the stratum corneum
- Use on thin skin areas such as the face

- Use on broken skin or other conditions where the skin barrier may be impaired
- In comparison with adults, children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic adverse effects. This is because children have an immature skin barrier and a greater surface area to body weight ratio compared with adults.

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. Therefore, treatment courses should be limited to five days and occlusion should not be used. If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye, as glaucoma and cataract might result from repeated exposure.

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.

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.

In infants and children under 12 years of age, 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.

Appropriate antimicrobial therapy should be used whenever treating inflammatory lesions which have become infected. Any spread of infection

requires withdrawal of topical corticosteroid therapy and systemic administration of antimicrobial agents. Bacterial infection is encouraged by the warm, moist conditions within skin folds or caused by induced by occlusive dressings, and so the skin should be cleansed before a fresh dressing is applied.

In rare instances, treatment of psoriasis with corticosteroids (or its withdrawal) is thought to have provoked the pustular form of the disease. Betamethasone valerate should be used with caution in patients with a history of local hypersensitivity to other corticosteroids. Betamethasone Valerate Cream is usually well tolerated but if signs of hypersensitivity appear, application should stop immediately. Local hypersensitivity reactions (*see section 4.8)* may resemble symptoms of the condition under treatment. Exacerbation of symptoms may occur.

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.

There have been a few reports in the literature of the development of cataracts in patients who have been using corticosteroids for prolonged periods of time. Although it is not possible to rule out systemic corticosteroids as a known factor, prescribers should be aware of the possible role of corticosteroids in cataract development.

Betamethasone Valerate Cream contains cetostearyl alcohol which can cause local skin reactions (e.g. contact dermatitis) and chlorocresol which may cause allergic reactions.

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.

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.

4.6 Fertility, pregnancy and lactation

Pregnancy

Avoid extensive use in pregnancy. There is inadequate evidence of safety. Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intrauterine growth retardation (see Section 5.3). There might therefore be a very small risk of such effects in the human foetus. Administration of betamethasone valerate during pregnancy should only be considered if the expected benefit to the mother outweighs the risk to the foetus. The minimum quantity should be used for the minimum duration.
This product should not be used during pregnancy or lactation unless considered essential by the physician.

Lactation

The safe use of topical corticosteroids during lactation has not been established.
It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable amounts in breast milk. Administration of betamethasone valerate during lactation should only be considered if the expected benefit to the mother outweighs the risk to the infant. If used during lactation betamethasone valerate should not be applied to the breasts to avoid accidental ingestion by the infant.

Fertility
There are no data in humans to evaluate the effect of topical corticosteroids on fertility.

4.7 Effects on ability to drive and use machines

There have been no studies to investigate the effect of betamethasone valerate on driving performance or the ability to operate machinery.

A detrimental effect on such activities would not be anticipated from the adverse reaction profile of topical betamethasone valerate.

4.8 Undesirable effects

Adverse events are listed below by MedDRA system organ class and frequency. Frequencies are defined as: very common (≥1/10), common (≥1/100 and <1/10), uncommon (≥1/1000 and <1/100), rare (≥1/10,000 and <1/1000), very rare (<1/10,000) including isolated reports and not known (cannot be estimated from the available data). 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.

Infections and Infestations

Very rare: Opportunistic infection

Immune system disorders

Very rare: Hypersensitivity, generalised rash

If signs of hypersensitivity appear, application should stop immediately.

Endocrine disorders

Very rare: Features of Cushing's syndrome.

Delayed weight gain/growth retardation in children, osteoporosis, glaucoma, hyperglycaemia/glucosuria, cataract, hypertension, increased weight/obesity, decreased endogenous cortisol levels, alopecia, trichorrhexis.

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 Special Warnings and Precautions for use). 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.

Eye disorders

Not known – Vision, blurred (see also section 4.4)

Skin and subcutaneous tissue disorders

Common: Local skin burning/skin pain and pruritus.

Very rare: Allergic contact dermatitis/dermatitis, erythema, rash, urticaria, local atrophic changes in the skin such as thinning*, skin wrinkling*, skin dryness*, striae* and dilatation of the superficial blood vessels (telangiectasias)* may be caused by prolonged and intensive treatment with highly active corticosteroid preparations, particularly when occlusive dressings are used or when skin folds are involved.

Pigmentation changes*, hypertrichosis, exacerbation of symptoms, pustular psoriasis (due to treatment of psoriasis with corticosteroids or its withdrawal: see Section 4.4. Special Warnings and Precautions for use)

Not known: Withdrawal reactions - redness of the skin which may extend to areas beyond the initial affected area, burning or stinging sensation, itch, skin peeling, oozing pustules. (see section 4.4)

General Disorders and Administration Site Conditions

Very rare: Application site irritation/pain

*Skin features secondary to local and/or systemic effects of hypothalamic-pituitary adrenal (HPA) axis suppression.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Topically applied betamethasone valerate may be absorbed in sufficient amounts to produce systemic effects. 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).

Treatment

In the event of overdose, betamethasone valerate should be withdrawn gradually by reducing the frequency of application, or by substituting a less potent corticosteroid because of the risk of glucocorticosteroid insufficiency.

Further management should be as clinically indicated or as recommended by the national poisons centre, where available.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: D07 AC01 (Corticosteroid, potent, (group III))

Mechanism of action

Topical corticosteroids act as anti-inflammatory agents via multiple mechanisms to inhibit late phase allergic reactions including decreasing the density of mast cells, decreasing chemotaxis and activation of eosinophils, decreasing cytokine production by lymphocytes, monocytes, mast cells and eosinophils, and inhibiting the metabolism of arachidonic acid.

Betamethasone is a corticosteroid with topical anti-inflammatory activity antipruritic, and vasoconstrictive properties.

5.2 Pharmacokinetic properties

Absorption

Topical corticosteroids can be systemically absorbed from intact healthy skin. The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the vehicle and the integrity of the epidermal barrier. Occlusion, inflammation and/or other disease processes in the skin may also increase percutaneous absorption.

Distribution

The use of pharmacodynamic endpoints for assessing the systemic exposure of topical corticosteroids is necessary because circulating levels are well below the level of detection.

Metabolism

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. They are metabolised, primarily in the liver.

Elimination

Topical corticosteroids are excreted by the kidneys. In addition, some corticosteroids and their metabolites are also excreted in the bile.

5.3 Preclinical safety data

Subcutaneous administration of betamethasone valerate to mice or rats at doses ≥0.1 mg/kg/day or rabbits at doses ≥12 micrograms/kg/day during pregnancy produced foetal abnormalities including cleft palate and intrauterine growth retardation.

The effect on fertility of betamethasone valerate has not been evaluated in animals.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol cetostearyl ether 20

Cetostearyl alcohol

Chlorocresol

Disodium hydrogen phosphate dodecahydrate

Citric acid monohydrate

Liquid paraffin

White soft paraffin

Purified water

6.2 Incompatibilities

None known

6.3 Shelf life

21 months.

In-use shelf life: 3 months

6.4 Special precautions for storage

Do not store above 30 °C.

6.5 Nature and contents of container

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

Pack sizes: 100g.

6.6 Special precautions for disposal

No special instructions.

7 MARKETING AUTHORISATION HOLDER

Accord Healthcare Limited
Sage House
319 Pinner Road
North Harrow
Middlesex
HA1 4HF
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 20075/0555

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

13/01/2025

10 DATE OF REVISION OF THE TEXT

13/01/2025