AUSTRALIAN PRODUCT INFORMATION – CELESTONE®-M (Betamethasone valerate) CREAM

1 NAME OF THE MEDICINE

Betamethasone valerate

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Celestone-M Cream contains betamethasone valerate equivalent to betamethasone 0.2mg/g.

Excipients with known effect
Celestone-M Cream contains cetostearyl alcohol and chlorocresol.

For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

Cream

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Celestone-M is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses such as atopic eczema, infantile eczema, nummular eczema, anogenital and senile pruritus, contact dermatitis, seborrhoeic dermatitis, neurodermatitis, solar dermatitis, stasis dermatitis and psoriasis.

Celestone-M is indicated for the maintenance therapy.

4.2 DOSE AND METHOD OF ADMINISTRATION

Apply a small amount to the affected area two or three times daily.

Refractory lesions of psoriasis and other deep seated dermatoses, such as chronic lichen simplex, hypertrophic lichen planus, atopic dermatitis, chronic eczematous and lichenified hand eruptions, recalcitrant pustular eruptions of the palms and soles, respond better if occlusive dressings are used.

Occlusive Dressings
Apply a layer of medication over the entire lesion under a light gauze dressing, cover with a pliable transparent, impermeable plastic material well beyond the edges of the treated area. Seal the edges to normal skin by adhesive tape or other means. Leave the dressing in place for 1 to 3 days and repeat the procedure three or four times as needed. Occasionally, a miliary eruption or folliculitis develops in the skin beneath the dressing and should be treated by removing the plastic covering and applying a topical antibiotic.

4.3 CONTRAINDICATIONS

Hypersensitivity to betamethasone valerate, other corticosteroids or any components in Celestone-M. Like other topical corticosteriods, Celestone-M is contraindicated in most viral infections of the skin, such as vaccinia, varicella and Herpes simplex, also tuberculosis and

acne rosacea.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Celestone-M should not be used in or near the eyes.

If irritation or sensitisation develops with the use of Celestone-M, treatment should be discontinued and appropriate therapy instituted.

In the presence of an infection, an appropriate antifungal or antibacterial agent should be administered. If a favourable response does not occur promptly, Celestone-M should be discontinued until the infection has been controlled adequately.

Any of the side effects that are reported following systemic use of corticosteroids, including adrenal suppression, may also occur with topical corticosteroids, especially in infants and children.

Systemic absorption of topical corticosteroids will be increased if extensive body surface areas are treated or if the occlusive technique is used. Suitable precautions should be taken under these conditions or when long-term use is anticipated, particularly in infants and children.

Visual disturbance may be reported with systemic and topical (including, intranasal, inhaled and intraocular) 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 of visual disturbances 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.

Paediatric use
Chronic corticosteroid therapy may interfere with the growth and development of children. Paediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and to exogenous corticosteroid effects than mature patients because of greater absorption due to a larger skin surface area to body weight ratio.

HPA axis suppression, Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include low plasma cortisol levels and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include a bulging fontanelle, headaches and bilaterial papilloedema.

Use in the elderly
No data available.

Effects on laboratory tests
No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

No data available.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility
No data available.

Use in Pregnancy (Category A)
Topical corticosteroids should not be used extensively on pregnant patients in large amounts or for prolonged periods of time.

Use in Lactation
Due to lack of data on the safety of betamethasone valerate in lactation, care should be exercised to ensure that the potential benefits to the lactating mother outweigh the possible hazards to the nursing infant.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

The following local adverse reactions have been reported with the use of topical corticosteroids, especially under occlusive dressings: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae and miliaria.

Rarely reported adverse effects include tingling, prickly skin/tightening or cracking of skin, warm feeling, laminar scaling and perilesional scaling, follicular rash, skin atrophy, erythema and telangiectasia.

Systemic adverse reactions, such as vision blurred, have also been reported with the use of topical corticosteroids.

Reporting suspected adverse effects
Reporting suspected adverse reactions after registration 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 at http://tga.gov.au/reporting-problems.

4.9 OVERDOSE

Symptoms
Excessive prolonged use of topical corticosteroids can suppress pituitary-adrenal function resulting in secondary adrenal insufficiency and produce manifestations of hypercorticism, including Cushing’s disease.

Treatment
Appropriate symptomatic treatment is indicated. Acute hypercorticoid symptoms are virtually reversible. Treat electrolyte imbalance, if necessary. In cases of chronic toxicity, slow withdrawal of corticosteroids is advised.

For information on the management of overdose, contact the Poison Information Centre on 131126 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action
Betamethasone valerate is a topically-active corticosteroid ester with anti-inflammatory,

antipruritic and vasoconstrictive actions.

Clinical trials
No data available.

5.2 PHARMACOKINETIC PROPERTIES

No data available.

5.3 PRECLINICALSAFETY DATA

Genotoxicity
No data available.

Carcinogenicity
No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

cetomacrogol 1000
cetostearyl alcohol
chlorocresol
liquid paraffin
monobasic sodium phosphate dihydrate
phosphoric acid
purified water
white soft paraffin

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C

6.5 NATURE AND CONTENTS OF CONTAINER

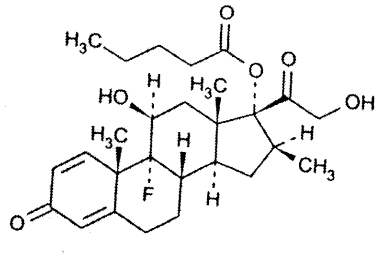
Celestone-M Cream, 0.02% (0.2 mg/g): 100g, Aluminium Tube

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy.

6.7 PHYSICOCHEMICAL PROPERTIES

Chemical structure



Betamethasone valerate is 9-fluoro-11β,21-dihydroxy-16β-methyl-3,20-dioxopregna-1,4-dien-17-yl pentanoate. The empirical formula is $C_{27}H_{37}FO_6$. MW = 476.6

CAS number

CAS Registry number is 2152-44-5

7 MEDICINE SCHEDULE (POISONS STANDARD)

Prescription Only Medicine (Schedule 4)

8 SPONSOR

Merck Sharp & Dohme (Australia) Pty Limited
Level 1 Building A, 26 Talavera Road,
Macquarie Park NSW 2113
Australia
www.msd-australia.com.au

9 DATE OF FIRST APPROVAL

8 October 1991

10 DATE OF REVISION

12 October 2018

Summary table of changes

Section changed	Summary of new information
4.4	Added information related to visual disturbances
4.8	Added “vision blurred” to the Adverse Reactions section
Heading	Relocated (Betamethasone valerate)
4.4	Added subheadings Use in the Elderly and Effects on laboratory tests
4.8	Added Reporting suspected adverse effects subheading

5.2	Deleted four subheadings and included No data available
6.5	Addition of Aluminium
8	Added web address