PRESCRIBING INFORMATION

PrCELESTODERM® V
Betamethasone valerate cream USP
Betamethasone valerate ointment USP
0.1%

PrCELESTODERM® V/2
Betamethasone valerate cream USP
Betamethasone valerate ointment USP
0.05%

Topical Corticosteroid

Bausch Health, Canada Inc.
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PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	All Non-Medicinal Ingredients
Topical	CELESTODERM V CREAM, betamethasone valerate, 1 mg (0.1%) betamethasone USP CELESTODERM V OINTMENT, betamethasone valerate, 1 mg (0.1%) betamethasone USP CELESTODERM V/2 CREAM, betamethasone valerate, 0.5 mg (0.05%) betamethasone USP CELESTODERM V/2 OINTMENT, betamethasone valerate, 0.5 mg (0.05%) betamethasone USP	Cream: Cetostearyl Alcohol, Chlorocresol, Mineral Oil, Monobasic Sodium Phosphate, Phosphoric Acid, Polyethylene Glycol 1000 Monocetyl Ether, Purified Water, Sodium Hydroxide and White Petrolatum. Ointment: White Petrolatum.

INDICATIONS AND CLINICAL USE

The topical management of allergic and inflammatory dermatoses responsive to corticosteroid therapy, such as psoriasis, atopic eczema, infantile eczema, nummular eczema, pruritus ani and vulvae, neurodermatitis (lichen simplex chronicus), intertrigo, contact dermatitis, seborrheic dermatitis, exfoliative dermatitis, solar dermatitis, stasis dermatitis and dyshidrosis. Refractory

psoriasis may be treated with CELESTODERM V (Betamethasone Valerate) especially in conjunction with the hydration technique of occlusive dressings.

The ointment formulations may be preferred for the treatment of dry, scaling and fissured lesions.

CELESTODERM V/2 (Betamethasone Valerate) contains a lower concentration (half strength) of betamethasone and is indicated for maintenance therapy after the acute phase has been brought under control, for less severe conditions and for extensive lesions involving large areas of the body surface.

CONTRAINDICATIONS

- Patients who are hypersensitive to betamethasone valerate or to any ingredient in the formulation or component of the container. For a complete listing, see the **DOSAGE FORMS, COMPOSITION AND PACKAGING** section of the Prescribing Information.
- Patients who are hypersensitive to other corticosteroids.
- Patients with viral (e.g. herpes or varicella) lesions of the skin, bacterial or fungal skin infections, parasitic infections, skin manifestations relating to tuberculosis or syphilis, eruptions following vaccinations.
- Topical application to the eye.

WARNINGS AND PRECAUTIONS

General

Patients should be advised to inform subsequent physicians of the prior use of corticosteroids.

When used under occlusive dressing, over extensive areas or on the face, scalp, axillae or scrotum, or for a prolonged period of time, sufficient absorption may occur to result in adrenal suppression and other systemic effects. In such cases, it is recommended that kidney function studies such as BUN be carried out prior to treatment and regularly throughout the course of the treatment. When long-term topical treatment under occlusive dressings is necessary, small dosages, rotation of sites and intermittent therapy should be considered (See **also Endocrine and Metabolism)**.

Cardiovascular

Suitable precautions should be taken when using topical corticosteroids in patients with stasis dermatitis and other skin diseases with impaired circulation.

Endocrine and Metabolism

Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-

adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients.

Conditions which augment systemic absorption include the application of topical corticosteroids over large body surface areas, prolonged use, or the addition of occlusive dressings. If patients must be treated over large body surface areas, they should be evaluated periodically for evidence of HPA axis suppression (see **Monitoring and Laboratory Test**). If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid.

Recovery of HPA axis function is generally prompt upon discontinuation of topical corticosteroids. Infrequently, signs and symptoms of glucocorticosteroid insufficiency may occur, requiring supplemental systemic corticosteroids. For information on systemic corticosteroid supplementation, see prescribing information for those products.

Paediatric patients may be more susceptible to systemic toxicity from equivalent doses because of their larger skin surface to body mass ratios (See **Special Populations-Paediatrics**).

Immune

Topical corticosteroids may increase the risk of infections including aggravation of cutaneous infection, masked infection and secondary infections. If concomitant skin infections develop, CELESTODERM V and CELESTODERM V/2 (Betamethasone Valerate) should be discontinued until the infection has been adequately controlled.

Ophthalmologic

Topical corticosteroids should be used with caution on lesions close to the eye because systemic absorption may cause increased intraocular pressure, glaucoma or cataracts.

Sensitivity

Allergic contact dermatitis with corticosteroids is usually diagnosed by observing a failure to heal rather than noticing a clinical exacerbation. Such an observation should be corroborated with appropriate diagnostic patch testing.

Skin

If significant irritation develops, CELESTODERM V and CELESTODERM V/2 should be discontinued and appropriate therapy instituted.

Prolonged use of topical corticosteroid preparations may produce striae or atrophy of the skin or subcutaneous tissue. Topical corticosteroids should be used with caution on lesions of the face, groin and axillae as these areas are more prone to atrophic changes than other areas of the body. Frequent observation is important if these areas are to be treated. If skin atrophy is observed, treatment should be discontinued.

Special Populations

Pregnant Women
Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at dosage levels that are similar to therapeutic doses. Some corticosteroids have been shown to be teratogenic after dermal application in laboratory animals.

There are no adequate and well-controlled studies of CELESTODERM V or CELESTODERM V/2 in pregnant women. CELESTODERM V and CELESTODERM V/2 should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus. Drugs of this class should not be used extensively in large amounts or for prolonged periods of time in pregnant patients.

Nursing mothers
Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Because many drugs are excreted in human milk, caution should be exercised when CELESTODERM V or CELESTODERM V/2 are administered to a nursing woman.

Paediatrics
Because of a higher ratio of skin surface area to body mass, paediatric patients are at a greater risk than adults of HPA axis suppression and Cushing's syndrome when they are treated with topical corticosteroids. They are therefore also at greater risk of adrenal insufficiency during and/or after withdrawal of treatment.

Adverse effects including striae have been reported with use of topical corticosteroids in infants and children. 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 an absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema. Chronic corticosteroid therapy may interfere with the growth and development of children.

Administration of topical corticosteroids to children should be limited to the least amount and for the shortest duration compatible with an effective therapeutic regimen.

Geriatrics (> 65 years of age)
In general, topical corticosteroids should be used cautiously in elderly patients, reflecting their increased skin fragility and greater frequency of hepatic, renal, or cardiac dysfunction, and of concomitant disease or other drug therapy.

Monitoring and Laboratory Tests

The cosyntropin ($ACTH_{1-24}$) stimulation test may be helpful in evaluating patients for HPA axis suppression.

ADVERSE REACTIONS

Adverse Drug Reaction Overview

The following local adverse reactions have been reported with topical corticosteroids and may occur more frequently with use of occlusive dressings. These reactions are listed in an approximate decreasing order of occurrence: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, skin atrophy, striae and miliaria.

Contact sensitivity to a particular dressing material or adhesive may occur occasionally.

Clinical Trial Adverse Drug Reactions

No data available.

Post-Market Adverse Drug Reactions

No data available.

DRUG INTERACTIONS

Drug-Drug Interactions

Interactions with other drugs have not been established.

Drug-Food Interactions

Interactions with foods have not been established.

Drug-Herb Interactions

Interactions with herbal products have not been established.

Drug-Laboratory Interactions

Interactions with laboratory tests have not been established.

DOSAGE AND ADMINISTRATION

Dosing Considerations

- Patients/caregivers should be instructed to use CELESTODERM V and CELESTODERM V/2 (Betamethasone Valerate) for the minimum amount of time necessary to achieve the desired results because of the potential for corticosteroids to suppress the hypothalamic-pituitary-adrenal (HPA) axis and cause skin atrophy (See **WARNINGS AND PRECAUTIONS**).

- CELESTODERM V and CELESTODERM V/2 are for **topical use** only and not for ophthalmic use.

- **Paediatrics**: Paediatric patients may be more susceptible to systemic toxicity from equivalent doses because of their larger skin surface to body weight ratios.

- **Geriatrics**: CELESTODERM V and CELESTODERM V/2 should be used with caution in patients> 65 years of age who may be more susceptible to percutaneous absorption and the potential effects of systemic absorption.

Recommended Dose and Dosage Adjustment

Apply a small amount on the affected skin 2 or 3 times daily. Refractory lesions of psoriasis and other deep-seated dermatoses such as lichen simplex chronicus, hypertrophic lichen planus, atopic dermatitis, chronic eczematous and lichenified hand eruptions, and recalcitrant pustular eruptions on the palms and soles will respond better to topical corticosteroids when used with the hydration technique of occlusive dressing. This technique reduces evaporation from the skin by means of a closed impermeable dressing over the lesion.

Occlusive dressing technique: (1) Apply a thick layer of the cream or ointment over the entire surface of the lesion under a light gauze dressing and then cover it with a pliable, transparent, impermeable, plastic material well beyond the treated area. (2) Seal the edges to the normal skin by adhesive tape or other means. (3) Leave the dressing in place 1 to 3 days and repeat the procedure 3 or 4 times as needed. With this method of treatment, marked improvement often is seen in a few days. Occasionally, a miliary eruption or folliculitis develops in the skin under the occlusive dressing requiring removal of the plastic covering.

Missed Dose

If a dose of this medication is missed, skip the missed dose and continue with the next scheduled dose.

Administration

Avoid contact with the eyes.

OVERDOSAGE

Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects. Excessive prolonged use may suppress hypothalamic-pituitary-adrenal (HPA) axis function, resulting in secondary adrenal insufficiency, which is usually reversible. Excessive prolonged use may also produce manifestations of hypercorticisim, including Cushing's disease. If toxic effects occur, treatment should be discontinued, and symptomatic therapy administered. Treat electrolyte imbalance, if necessary. In case of chronic toxicity, slow withdrawal of corticosteroids is advised (see **WARNINGS and PRECAUTIONS**).

For management of a suspected drug overdose, contact your regional Poison Control Centre.

ACTION AND CLINICAL PHARMACOLOGY

No data available.

STORAGE AND STABILITY

Store between 15 and 30ºC.

Keep out of reach of children and pets. Unused medication should not be disposed of down the drain or in household waste.

DOSAGE FORMS, COMPOSITION AND PACKAGING

CELESTODERM V Cream
Each g of cream contains betamethasone valerate USP, equivalent to 1 mg (0.1%) betamethasone USP in a water-miscible base. Non-medicinal ingredients: Cetostearyl Alcohol, Chlorocresol, Mineral Oil, Monobasic Sodium Phosphate, Phosphoric Acid, Polyethylene Glycol 1000 Monocetyl Ether, Purified Water, Sodium Hydroxide and White Petrolatum. Jars of 450 g.

CELESTODERM V Ointment
Each g of ointment contains betamethasone valerate USP, equivalent to 1 mg (0.1%) betamethasone USP in White Petrolatum. Non-medicinal ingredients: White Petrolatum. Jars of 450 g.

CELESTODERM V/2 Cream
Each g of cream contains betamethasone valerate USP, equivalent to 0.5 mg (0.05%) betamethasone USP, in a water-miscible base. Non-medicinal ingredients: Cetostearyl Alcohol, Chlorocresol, Mineral oil, Monobasic Sodium Phosphate, Phosphoric Acid, Polyethylene Glycol 1000 Monocetyl Ether, Purified Water, Sodium hydroxide and white petrolatum. Jars of 450 g.

CELESTODERM V/2 Ointment
Each g of ointment contains betamethasone valerate USP, equivalent to 0.5 mg (0.05%)

betamethasone USP in white petrolatum. Non-medicinal ingredients: White Petrolatum. Jars of 450 g.

Last Revised: September 29, 2020