

CELESTODERM*-V WITH GARAMYCIN*

Schering-Plough

Cream/Ointment

DESCRIPTION

CELESTODERM-V WITH GARAMYCIN Cream / Ointment provide in each gram betamethasone valerate, equivalent to 1.0 mg (0.1%) betamethasone alcohol and gentamicin sulfate equivalent to 1.0 mg (0.1%) gentamicin base.

Inactive ingredients

Cream: chlorocresol, monobasic sodium phosphate, phosphoric acid, phosphoric acid, white petrolatum, mineral oil, polyethylene glycol, monocetyl ether, cetostearyl alcohol, and purified water.

Ointment: white petrolatum

ACTIONS

Betamethasone valerate is effective because of its anti-inflammatory, antipruritic and vasoconstrictive actions.

Gentamicin, a wide-spectrum bactericidal antibiotic, is effective topically against a broad spectrum of common pathogens. Susceptible bacteria include sensitive strains of **Streptococci** (group A beta hemolytic, alpha hemolytic), **Staphylococcus aureus** (coagulase positive, coagulase negative and some penicillinase producing strains) and the gram-negative bacteria: **Pseudomonas aeruginosa**, **Aerobacter aerogenes**, **Escherichia coli**, **Proteus vulgaris** and **Klebsiella pneumoniae**.

INDICATIONS AND USAGE

CELESTODERM-V WITH GARAMYCIN Cream/Ointment is indicated in the topical treatment of corticosteroid-responsive dermatoses when complicated by secondary infection

caused by organisms sensitive to gentamicin or when the possibility of such infections is suspected. Such disorders include: eczema (atopic, infantile, nummular) anogenital and senile pruritus, contact dermatitis (dermatitis venenata), seborrheic dermatitis, neurodermatitis, intertrigo, solar dermatitis, exfoliative dermatitis, stasis dermatitis and psoriasis.

DOSAGE AND ADMINISTRATION

A thin film of CELESTODERM-V WITH GARAMYCIN Cream/Ointment should be applied to cover completely the affected area two or three times daily.

Frequency of application should be determined by the physician according to the severity of the condition. While mild cases have responded to once-a-day application, more severe cases may require more frequent application.

ADVERSE REACTIONS

The following local adverse reactions have been reported with the use of topical corticosteroids: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis and allergic contact dermatitis.

The following may occur more frequently with occlusive dressings: maceration of the skin, secondary infection, skin atrophy, striae and miliaria.

Treatment with gentamicin has produced transient irritation (erythema and pruritus) that usually did not require discontinuance of treatment.

CONTRAINDICATIONS

CELESTODERM-V WITH GARAMYCIN-V Cream/Ointment is contraindicated in those patients with a history of sensitivity reactions to any of its components.

PRECAUTIONS

If irritation or sensitization develops with the use of CELESTODERM-V WITH GARAMYCIN Cream/Ointment, treatment should be discontinued and appropriate therapy instituted.

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 treat-

ed 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. Brand of betamethasone valerate and gentamicin sulfate.

Use of topical antibiotics occasionally allows overgrowth of nonsusceptible organisms, including fungi. If this occurs or if irritation, sensitization or superinfection develops, treatment with CELESTODERM-V WITH GARAMYCIN should be discontinued and appropriate therapy instituted.

Systemic absorption of topically applied gentamicin may be increased if extensive body surface areas are treated, especially over prolonged time periods or in the presence of dermal disruption. In these cases, the undesirable effects which occur following systemic use of gentamicin may potentially occur. Cautious use is recommended under these conditions, particularly in infants and children.

CELESTODERM-V WITH GARAMYCIN Cream/
Ointment is not for ophthalmic use.

Pediatric Use

Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced hypothalamic-pituitary-adrenal (HPA) axis suppression and to exogenous corticosteroid effects than mature patients because of greater absorption due to a large 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 bilateral papilledema.

USE DURING PREGNANCY AND IN NURSING WOMEN

Since safety of topical corticosteroid use in pregnant women has not been established, drugs of this class should be used during pregnancy only if the poten-

tial benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively in large amounts or for prolonged periods of time in pregnant patients.

Since it is not known whether topical administration of corticosteroids can result in sufficient systemic absorption to produce detectable quantities in breast milk, a decision should be made to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

OVERDOSAGE

Symptoms

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

A single overdose of gentamicin would not be expected to produce symptoms.

Excessive prolonged use of topical gentamicin may lead to overgrowth of lesions by fungi or nonsusceptible bacteria.

Treatment

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

Appropriate antifungal or antibacterial therapy is indicated if overgrowth occurs.

HOW SUPPLIED

CELESTODERM-V WITH GARAMYCIN Cream
15 gm. tubes

CELESTODERM-V WITH GARAMYCIN Ointment
15 gm. tubes

STORAGE

Store between 2°C and 30°C

*Trademarks