SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

CELESTODERM-V® with GARAMYCIN

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

***Composition*:** *active ingredients:* betamethasone, gentamycin;
1 g of cream contains betamethasone valerate, equivalent to 1.0 mg betamethasone and gentamicin sulfate equivalent to 1.0 mg gentamicin base.
excipients: white soft paraffin, cetostearyl alcohol, liquid paraffin, macrogol cetostearyl ether, sodium dihydrogen phosphate dihydrate, chlorocresol, phosphoric acid, acid phosphoric/sodium hydroxide, purified water.

3. PHARMACEUTICAL FORM

Cream.

Pharmacotherapeutic group.
Corticosteroids, dermatological preparations. Corticosteroids, combinations with antibiotics. Betamethasone and antibiotics. ATC code: D07C C01.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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: eczema (atopic, infantile, nummular), anogenital and senile pruritus, contact dermatitis, seborrheic dermatitis, neurodermatitis, intertrigo, solar dermatitis, exfoliative dermatitis, stasis dermatitis and psoriasis.

4.2 Posology and method of administration

A thin film of cream should be applied to cover completely the affected skin areas twice daily, in the morning and at night.
Frequency of application should be determined individually according to the severity of the condition. Mild cases have responded to once-a-day application, more severe cases may require more frequent application. Duration of therapy varies depending upon the extent and location of disease and patient response. However, if clinical improvement is not achieved by three to four weeks, diagnosis should be reviewed.

4.3 Contraindications

The established infections of a skin (virus, bacterial including cutaneous tuberculosis, acute dermatomycosis), acne. The drug is contraindicated in patients with hypersensitivity to any of active components or to any other ingredient in this preparation.

4.4 Special warnings and precautions for use

Celestoderm-V® with Garamycin cream is not for ophthalmic use.
If irritation or sensitization develops with the use of Celestoderm-V® with Garamycin cream, 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.
Cross-allergenicity among aminoglycosides has occurred.

Systemic absorption of topical corticosteroids will be increased if extensive body surface areas are treated or if occlusive dressings are used, especially over prolonged time periods. Suitable precautions should be taken under these conditions, particularly in infants and children.
Systemic absorption of topically applied gentamicin will 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.
Prolonged use of topical antibiotics occasionally may result in overgrowth of nonsusceptible microorganisms, including fungi. If this occurs or if irritation, sensitization or superinfection develops, treatment should be discontinued and appropriate therapy should be instituted.

4.5 Interaction with other medicinal products and other forms of interaction

The drug can reduce durability of latex on a stretching.

4.6 Fertility, pregnancy and lactation

Pregnancy and lactation.
Safety of topical corticosteroid use in pregnant women has not been established. Drugs of this class should be used during pregnancy only if the potential 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.
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.

Pediatric use. Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced hypothalamic-pituitary-adrenal 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. Hypothalamic-pituitary-adrenal 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.

4.7 Effects on ability to drive and use machines

Generally the drug has no effects on ability to drive and use machines.

4.8 Undesirable effects

Adverse reactions. Adverse reactions to the drug therapy have been reported very rarely and include hypersensitization, eruption and skin pigmentation.
Prolonged use and/or use in large doses, applying in the presence of dermal disruption may lead to effects, such as skin atrophy, telangiectasia, striae, steroidal acne, rosacea, perioral dermatitis and hypertrichosis. It is necessary to consider possibility of development of system effects (hypocorticism, diabetes, osteoporosis).
Treatment with gentamicin has produced transient irritation (erythema and pruritus) that usually did not require discontinuance of treatment.
The following adverse reactions may occur with the use of topical corticosteroids under occlusive dressings: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis and allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae and miliaria.

4.9 Overdose

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 syndrome.
A single overdose of gentamicin did not result to manifestations of overdose symptoms. Excessive prolonged use of topical gentamicin may lead to overgrowth of antibiotic-resistant microorganisms.
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. If overgrowth of resistant microorganisms occurs, the drug should be discontinued and appropriate therapy should be instituted.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Celestoderm-V® with Garamycin combines long-term anti-inflammatory, antipruritic and vasoconstrictive actions of betamethasone valerate with wide-spectrum bactericidal antibiotic activity of gentamicin sulfate. Gentamycin is active against *Staphylococcus aureus* (methicillin-susceptible strains) and the gram-negative bacteria: *Aerobacter aerogenes*, *Escherichia coli*, *Proteus vulgaris* and others.

5.2 Pharmacokinetic properties

There are no data on pharmacokinetic properties of Celestoderm-V® with Garamycin.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

excipients: white soft paraffin, cetostearyl alcohol, liquid paraffin, macrogol cetostearyl ether, sodium dihydrogen phosphate dihydrate, chlorocresol, phosphoric acid, acid phosphoric/sodium hydroxide, purified water.

Main physical/chemical properties: soft, homogeneous, white to off-white cream without foreign inclusion.

6.2 Shelf life

3 years.

6.3 Storage

Keep away from children, store at the temperature not above 25^{o}C.

6.4 Container.

15 g or 30 g in tubes of aluminum. One tube in carton box.

7. MARKETING AUTHORISATION HOLDER

Schering-Plough Central East AG
Weystrasse 20
CH-6000 Lucerne 6

Switzerland