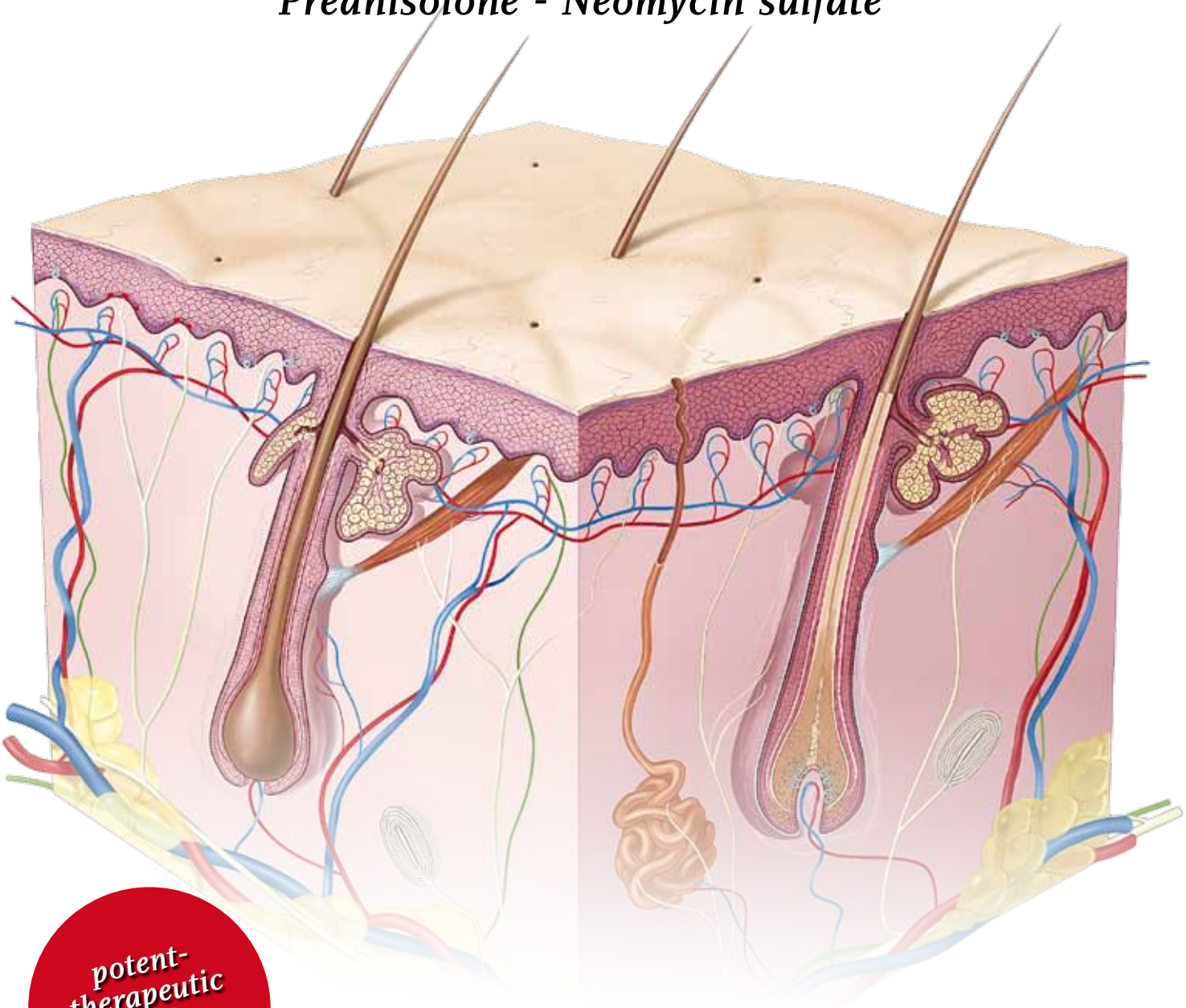
Dermol

Prednisolone - Neomycin sulfate



potent-
therapeutic
and
relieving

...for skin treatment

assures excellent penetration and absorption for the treatment of cellular subcellular membranes

Cream 20g.
Ointment 20g.

Dermol

Prednisolone - Neomycin sulfate

Indications	**For the therapeutic treatment of allergic dermatosis**
Pharmacodynamic properties	**Combination of an active corticosteroid which exhibits anti-inflammatory, antipruritic and vasoconstrictor action and an antibiotic which is topically used for the treatment of skin infections**
Dosage	**applied 2-3 times a day**

SPC
SUMMARY OF PRODUCT CHARACTERISTICS
DERMOL
CREAM 0.5% +0.5%
OINTMENT 0.5% + 0.5%
(PREDNISOLONE + NEOMYCIN SULFATE)

1. NAME OF THE MEDICINAL PRODUCT
DERMOL

2. QUALITATIVE AND QUANTITATIVE COMPOSITION IN ACTIVE INGREDIENT
Each gram of the cream or ointment contains 5 mg of prednisolone and 5 mg of neomycin sulfate.

3. PHARMACEUTICAL FORM
Cream
Ointment

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
For the therapeutic treatment of allergic dermatosis.

4.2 Dosage and method of administration
Adults: Following cleansing of the affected site, a small quantity of cream or ointment is applied 2-3 times a day depending on the nature of dermatosis.
Children: same as adults.
Elderly: same as adults.

4.3 Contraindications
Hypersensitivity to the active substances or any of the ingredients of the product.
Pharmaceutical products of corticosteroids topically applied should not be used in the case of undiagnosed dermatosis. Their use should be avoided in the cases of acme, perioral dermatitis, flabby ulcers and burns as they inhibit healing.
DERMOL is also contraindicated in the following cases:
- During pregnancy, especially during the first months (except for the case of substitution therapy in Addison's disease and the case of congenital adrenal hyperplasia).
- In patients with severe renal disease (with the exception of nephrosis).
- In patients with psychosis or predisposition to psychosis.
- In patients with active tuberculosis (with the exception of special cases).
- In patients with infectious diseases (with the exception of special cases).
- In patients with hemorrhagic disposition (with the exception of special cases).

Furthermore, there are ophthalmic contraindications and the use of corticosteroids should be avoided when vaccination is going to be performed.
Corticosteroids are contraindicated in the presence of herpes simplex. They may also cause cataract and increase of the intraocular pressure (in rare cases, clinical picture of pseudotumor cerebri may be observed).
Finally, corticosteroids are contraindicated in patients with gastroduodenal ulcer, systemic mycosis, heart disease or hypertension with congestive heart failure, osteoporosis and diabetes mellitus.

4.4 Special warnings and precautions during use
Long-term use in children should be avoided.
Children are more susceptible to systemic adverse effects due to the use of topical corticosteroids as they may absorb greater drug quantities because of the greater skin surface area to body weight ratio.
When a dry dressing is applied, skin should be cleaned in order to avoid a possible transfection.
Topical corticosteroids should not be used for more than 3 weeks without the dermatologist's re-examination.
After repeated application of at least 10-15 days, temporary reduction or loss of the corticosteroids efficacy (especially that of the fluoridated corticosteroids) may be observed. This phenomenon is restored after discontinuation of the treatment for a few days or weeks.
Due to the undesirable effects that may occur as a result of a possible absorption, caution is required when Dermol is applied to large skin surface areas or for a prolonged period of time, particularly in children and in patients with renal diseases, hemorrhagic disposition and in cases of imminent vaccinations.
Generally, the less potent corticosteroid, that is considered to be effective for the intended indication, should be chosen and in case of non-response, another corticosteroid of the same or greater potency should be administered.
Dermol may cause catarract and glaucoma if used in the area near the eyes for a prolonged period of time.
If it is used topically on the eyelids, caution is required in order to reassure that the dug will not get in contact with the eyes.

4.5 Interactions with other medicinal products and other forms of interaction
Concomitant use of corticosteroids with phenytoin, phenobarbital, ephedrine and rifampicin may reduce the efficacy of the corticosteroids. Alcohol and non-steroidal anti-inflammatory agents (NSAIAs) enhance their ulcerogenic effect. Concurrent use of corticosteroids with potassium-depleting diuretics may result in severe hypokalemia, whereas concurrent use with digitalis may increase the possibility of digitalis toxicity (associated with hypokalemia). Steroids either decrease or enhance the effects of coumarin-derivative anticoagulants.

4.6 Pregnancy and lactation
The use of DERMOL during pregnancy should be avoided. Topical corticosteroids should be administered during pregnancy only if the expected benefit outweighs the possible risk to the fetus. In such cases, they should not be administered in large quantities or for a prolonged period of time.
The use of DERMOL during lactation should be avoided. When the use of corticosteroids during lactation is judged to be necessary, the quantity of the drug and the duration of treatment should be limited to the minimum.

4.7 Effects on ability to drive and use machines
None known.

4.8 Undesirable effects
General - after long-term use
Both natural glucocorticoids as well as their synthetic derivatives cause undesirable effects of the same degree at equivalent doses. Thus, long-term, mostly, administration may result in significant undesirable effects, the major of which are the following:
hypothalamo-pituitary-adrenal axis suppression, decrease of cortisol serum levels-Cushing's syndrome, hyperglycemia and glycosuria, water and sodium retention, hypokalemia, hirsutism syndrome and acme, retardation of surgical wounds and injuries healing, hypertension, negative nitrogen and calcium balance with osteoporosis, peptic ulcer, psychotic manifestations, increase of the intraocular pressure and glaucoma. Catarract, sensitivity to infections and spreading of microbial inflammations, decreased growth rate in children, benign intracranial hypertension, deregulation of diabetes mellitus, masking of acute surgical abdomen (silent peritonitis in cases of puncture).

4.9 Overdose
The treatment of toxic reactions is symptomatic.

5. PHARMACOLOGICAL PROPERTIES
ATC code: D07CA03

GENERAL
Penetration and topical effect
Corticosteroids must penetrate skin in order to act topically.
The extent of the absorption and the clinical action as well as most undesirable effects have been proved to be dependent of the active ingredient itself and also various factors for a certain corticosteroid.

5.1 Pharmacodynamic properties
Prednisolone is an active corticosteroid which exhibits anti-inflammatory, antipruritic and vasoconstrictor action, when topically applied.
Neomycin is an antibiotic which is topically used for the treatment of skin infections.
Neomycin sulfate is a broad spectrum antibiotic with bactericidal action against many bacteria and especially staphylococcus aureus and proteus.
Topical corticosteroids exhibit anti-inflammatory action. They suppress manifestations of inflammatory reaction such as edema, fibrin deposition, capillary dilatation, leukocytes migration, capillary proliferation, collagen deposition, fibroblast proliferation and scarring. Steroids inhibit inflammatory reaction against mechanical, chemical or immunological factors.
The mechanism of the anti-inflammatory action is considered to operate through the intensification of the vassopressor action of adrenaline, the stabilization of the membrane of lysosomes, the retardation of the macrophages motility, the inhibition of quinine release, the inhibition of the lymphocytes and neutrophils function as well as the prostaglandins synthesis and the reduction of antibodies production during long-term use.

Drug concentration
Further increase of the concentration, after a certain concentration of the drug in a given inactive base, does not result in proportionally greater potency but on the contrary, it increases the appearance of undesirable effects.

Pharmaceutical form
The penetration of the active ingredient depends on the physicochemical properties of the base. The presence of other ingredients/excipients may influence the penetration through the stratum corneum or/and the result (e.g. salicylic acid, urea, propylene glycol, antibiotics and antiseptics, pitch).

Application area
The limited penetration of the drug in areas such as soles and palms is owed to their thick stratum corneum. For the opposite reasons, rapid and significant absorption may be observed through e.g. the mucosa of the scrotal skin, the skin of the eyelids and to a lesser degree, the skin of the forehead and the scalp.

Skin condition
Penetration is increased when applying on damaged or affected skin (e.g. erosions or pathological conditions such as parakeratosis). However, the damaged or affected stratum corneum is restored after a few days treatment.

Application conditions
Dressing enhances penetration and it may happen unintentionally when infant diapers are used or when intertriginous areas or creases are rubbed.
The effect of these various factors should be taken into consideration during clinical studies.

5.2 Pharmacokinetic properties
a. General characteristics
The extent of absorption of topical corticosteroids is defined by many factors such as the concentration of the drug, its pharmaceutical form, the excipients, the application area (difficulty of absorption in thick stratum corneum), the skin condition (increase of absorption in damaged skin) and the use of dry occlusion (substantial increase of absorption). After their absorption by the skin, topical corticosteroids follow the pharmacokinetics of those systemically administered.
They are bound to a variable extent with plasma proteins.
They are metabolized mainly by the liver and excreted via the kidneys. Some of the topical corticosteroids and their metabolites are also excreted via the bile.
Long-term use of glucocorticoids leads, as already mentioned, to hypothalamo-pituitary-adrenal axis suppression, that is, to inhibition of the adrenocortical function. The extent of this inhibition is dependent to the dose, the potency of the administered corticosteroid, the frequency and the time of its administration within the day, its half-life in the tissues and the total duration of the treatment. It is noted that the suppressive effect of the glucocorticoids on the hypothalamo-pituitary-adrenal axis is more intense and prolonged when they are administered during nighttime. In normal subjects, a dose of 1 mg of dexamethasone administered at night, inhibits the secretion of the adrenocorticotropic hormone of the pituitary for 24 hours. Sudden or abrupt reduction of the dose of glucocorticoids may cause withdrawal syndrome which is characterized by acute adrenocortical insufficiency with muscle weakness, hypotension, hypoglycaemia, nausea, vomiting, restlessness, myalgia, arthralgia.

b. Patient characteristics
The presence of topical inflammation requires medical monitoring.

5.3 Pre-clinical safety data (toxicological data)
Acute and chronic toxicity: those mentioned to the topical and general systemic use of steroids.

Mutagenic action-oncogenesis
The action of topically administered corticosteroids has not been studied. Mutagenicity studies with Prednisolone and Hydrocortisone have given negative results.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Cream:
Cetyl alcohol, white soft paraffin, liquid paraffin, polysorbate 60, sorbitan monostearate, methyl hydroxybenzoate, propyl hydroxybenzoate, propylene glycol, sodium metabisulfite, disodium phosphate, water demineralised
Ointmenrt: white soft paraffin, liquid paraffin

6.2 Incompatibilities
Not reported.

6.3 Shelf life
24 months.

6.4 Special storage precautions
Keep at temperature below 25oC in a dry place, protected from light, out of reach and sight of children.

6.5 Nature and contents of the container
Aluminum tube (TUB x 20 G) packaged in a carton box.

6.6 Instructions for use and handling
Not necessary.

6.7 Marketing Authorization Holder-Manufacturer
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6.8 Exceptional Marketing Authorization Holder in Cyprus
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Exceptional Marketing Authorizaton No in Cyprus: S00779

7. MARKETING AUTHORIZATION NUMBER
DERMOL CREAM: 8482/6-2-2007
DERMOL OINTMENT: 8482/6-2-2007

8. DATE OF FIRST MARKETING AUTHORIZATION
DERMOL CREAM: 26-5-1964
DERMOL OINTMENT: 31-8-1961

9. DATE OF (PARTIAL) REVISION OF THE TEXT
01/2012

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