SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

DERMOVATE 0.05% w/w Cream and Ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of cream contains 0.5 mg of clobetasol propionate (0.05% w/w).

Excipients with known effect:

Each gram of cream contains:

- Propylene glycol
- Cetostearyl alcohol
- Chlorocresol

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cream.
White to off-white cream.

Ointment
Translucent to white soft smooth ointment.

4. Clinical particulars

4.1 Therapeutic indications

DERMOVATE is a very potent topical corticosteroid indicated for adults, elderly and children over 1 year for the relief of the inflammatory and pruritic manifestations of steroid responsive dermatoses.
These include the following:
-Psoriasis (excluding widespread plaque psoriasis).
-Recalcitrant dermatoses
-Lichen planus
-Discoid lupus erythematosus
-Other skin conditions which do not respond satisfactorily to less potent steroids

4.2 Posology and method of administration

Posology

Adults, Elderly and Children over 1 year:

Apply thinly and gently rub in using only enough to cover the entire affected area once or twice a day for up to 4 weeks until improvement occurs. Thereafter, reduce frequency or change to a less potent preparation. Maximum weekly dose should not exceed 50 g.

Repeated short courses may be used to control exacerbations. Occlusion may enhance effect in resistant lesions.

Children under 1 year:
Contraindicated.

Elderly:
Use minimal quantity for shortest duration due to possible delayed elimination from decreased hepatic/renal function.

Renal/Hepatic Impairment:

Use minimal quantity for shortest duration due to risk of systemic toxicity.

Method of administration
Cutaneous use only. Ensure adequate absorption before applying emollients.

4.3 Contraindications

- Untreated cutaneous infections
- Rosacea
- Acne vulgaris
- Perianal and genital pruritus
- Perioral dermatitis
- Pruritus without inflammation
- Children under 1 year (including dermatitis)

4.4 Special warnings and precautions for use

Use with caution in patients with history of local hypersensitivity. Risk of systemic absorption and hypercortisolism. Minimize use and avoid long-term application. Occlusion increases risk.

Children may absorb more and be more susceptible to systemic effects.

Visual disturbances including cataract, glaucoma, and central serous chorioretinopathy reported. Avoid use on face or eyelids. If applied to face, limit duration.

Risk of rebound flares (topical steroid withdrawal syndrome) upon discontinuation.

Infection risk is increased with occlusion.

In psoriasis, use with caution under supervision.

If infection occurs, withdraw corticosteroid and treat infection.

May increase risk of local reactions in chronic leg ulcer dermatitis.

Contains paraffin—avoid contact with open flames.

4.5 Interaction with other medicinal products and other forms of interaction

Co-administration with CYP3A4 inhibitors (e.g., ritonavir, itraconazole) may increase systemic exposure.

4.6 Pregnancy and Lactation

Fertility:

There are no data in humans to evaluate the effect of topical corticosteroids on fertility. Clobetasol administered subcutaneously to rats had no effect upon mating performance; however, fertility was decreased at the highest dose (see Non-Clinical Information)

Pregnancy:

There are limited data from the use of DERMOVATE in pregnant women.

Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development (see Non-Clinical Information).

The relevance of this finding to humans has not been established. Administration of DERMOVATE during pregnancy should only be considered if the expected benefit to the mother outweighs the risk to the foetus. The minimum quantity should be used for the minimum duration.

Lactation:

The safe use of topical corticosteroids during lactation has not been established.

It is not known whether the topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable amounts in breast milk. Administration of DERMOVATE during lactation should only be considered if the expected benefit to the mother outweighs the risk to the infant.

If used during lactation DERMOVATE should not be applied to the breasts to avoid accidental ingestion by the infant.

4.7 Effects on ability to drive and use machines

There have been no studies to investigate the effect of *DERMOVATE* on driving performance or the ability to operate machinery. A detrimental effect on such activities would not be anticipated from the adverse reaction profile of topical *DERMOVATE*.

4.8 Undesirable effects

Adverse Reactions

Adverse drug reactions (ADRs) are listed below by MedDRA system organ class and by frequency. Frequencies are defined as: very common (≥1/10), common (≥1/100 and <1/10), uncommon (≥1/1,000 and <1/100), rare (≥1/10,000 and <1/1,000) and very rare (<1/10,000), including isolated reports.

Post-marketing data

Infections and Infestations

Very rare	Opportunistic infection

Immune System Disorders

Very rare	Local Hypersensitivity

Endocrine Disorders

Very rare	Hypothalamic-pituitary adrenal (HPA) axis suppression:
	Cushingoid features: (e.g. moon face, central obesity), delayed weight gain/growth retardation in children, osteoporosis, hyperglycaemia/glucosuria, hypertension, increased weight/obesity, decreased endogenous cortisol levels, alopecia, trichorrhexis

Eye Disorders

Very rare	Cataract, central serous chorioretinopathy, glaucoma

Skin and Subcutaneous Tissue Disorders

Common	Pruritus, local skin burning /skin pain
Uncommon	Skin atrophy*, striae*, telangiectasias*
Very rare	Skin thinning*, skin wrinkling*, skin dryness*, pigmentation changes*, hypertrichosis, exacerbation of underlying symptoms, allergic contact dermatitis/dermatitis, pustular psoriasis, erythema, rash, urticaria, acne
Not Known:	Withdrawal reactions - redness of the skin which may extend to areas beyond the initial affected area, burning or stinging. sensation, itch, skin peeling, oozing pustules. (See section warnings & precautions)

General Disorders and Administration Site Conditions

Very rare	Application site irritation/pain

**Skin features secondary to local and/or systemic effects of hypothalamic-pituitary adrenal (HPA) axis suppression.*

4.9 Overdose

Symptoms and signs

Topically applied *DERMOVATE* may be absorbed in sufficient amounts to produce systemic effects. Acute overdosage is very unlikely to occur, however, in the case of chronic overdosage or misuse the features of hypercortisolism may occur (*see Adverse Reactions*).

Treatment

In the event of overdose, *DERMOVATE* should be withdrawn gradually by reducing the frequency of application or by substituting a less potent corticosteroid because of the risk of glucocorticosteroid insufficiency.

Further management should be as clinically indicated or as recommended by the national poisons centre, where available.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

ATC code

D07AD Corticosteroids, very potent (group IV)

Mechanism of action

Topical corticosteroids act as anti-inflammatory agents via multiple mechanisms to inhibit late phase allergic reactions including decreasing the density of mast cells, decreasing chemotaxis and activation of eosinophils, decreasing cytokine production by lymphocytes, monocytes, mast cells and eosinophils, and inhibiting the metabolism of arachidonic acid.

Pharmacodynamic effects

Topical corticosteroids have anti-inflammatory, antipruritic, and vasoconstrictive properties.

5.2 Pharmacokinetic properties

Absorption

Topical corticosteroids can be systemically absorbed from intact healthy skin. The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the vehicle and the integrity of the epidermal barrier. Occlusion, inflammation and/or other disease processes in the skin may also increase percutaneous absorption.
Mean peak plasma clobetasol propionate concentrations of 0.63 nanograms/ml occurred in one study eight hours after the second application (13 h after an initial application) of 30 g clobetasol propionate 0.05 % ointment to normal individuals with healthy skin. Following the application of a second dose of 30 g clobetasol propionate cream 0.05 %, mean peak plasma concentrations were slightly higher than the ointment and occurred 10 h after application. In a separate study, mean peak plasma concentrations of approximately 2.3 nanograms/ml and 4.6 nanograms/ml occurred respectively in patients with psoriasis and eczema three hours after a single application of 25 g clobetasol propionate 0.05 % ointment.

Distribution

The use of pharmacodynamic endpoints for assessing the systemic exposure of topical corticosteroids is necessary due to the fact that circulating levels are well below the level of detection.

Metabolism

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. They are metabolised, primarily in the liver.

Elimination

Topical corticosteroids are excreted by the kidneys. In addition, some corticosteroids and their metabolites are also excreted in the bile.

5.3 Preclinical safety data

Non-Clinical Information

Carcinogenesis / Mutagenesis

Carcinogenesis

Long-term animal studies have not been performed to evaluate the carcinogenic potential of clobetasol propionate.

Genotoxicity

Clobetasol propionate was not mutagenic in a range of *in vitro* bacterial cell assays.

Reproductive Toxicology

Fertility

In fertility studies, subcutaneous administration of clobetasol propionate to rats at doses of 6.25 to 50 micrograms/kg/day produced no effects on mating, and fertility was only decreased at 50 micrograms/kg/day.

Pregnancy

Subcutaneous administration of clobetasol propionate to mice (≥100 micrograms/kg/day), rats (400 micrograms/kg/day) or rabbits (1 to 10 micrograms/kg/day) during pregnancy produced foetal abnormalities including cleft palate and intrauterine growth retardation.

In the rat study, where some animals were allowed to litter, developmental delay was observed in the F1 generation at ≥100 micrograms/kg/day and survival was reduced at 400 micrograms/kg/day. No treatment-related effects were observed in F1 reproductive performance or in the F2 generation.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cream:

Glyceryl monostearate
Cetostearyl alcohol
Chlorocresol
Sodium citrate
Citric acid (monohydrate)
Purified water
Arlacel 165
Beeswax substitute 6621
Propylene glycol.

Ointment:

Propylene glycol
White soft paraffin
Sorbitan sesquioleate.
For important information about some of these excipients *see Warnings and Precautions.*

6.2 Incompatibilities

No incompatibilities have been identified.

6.3 Shelf life

The expiry date is indicated on the packaging.

6.4 Special precautions for storage

The storage conditions are detailed on the packaging

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

Cream

Collapsible aluminium tubes, coated internally with an epoxy resin based lacquer and closed with a cap.

Ointment

Collapsible aluminium tubes, coated internally with an epoxy resin based lacquer or unlacquered and closed with a cap.

6.6 Special precautions for disposal <and other handling>

Use and Handling

There are no special requirements for use or handling of this product.

Not all presentations are available in every country.

7. APPLICANT/MANUFACTURER

Adapted from

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Manufactured by:
Delpharm Poznań Spółka Akcyjna
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Manufactured for:
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