New Zealand Data Sheet

1. PRODUCT NAME

DP LOTION-HC 1%

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

DP LOTION-HC 1% contains Hydrocortisone 1% w/w.

Excipient(s) with known effect

DP LOTION-HC 1% contains lanolin, cetyl alcohol, and parabens (as preservatives).
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Uniformly white, glossy, moderately viscous lotion.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

DP LOTION-HC 1% is indicated as adjunctive therapy for the symptomatic relief of the inflammatory manifestations of corticosteroid responsive dermatoses.

4.2. Dose and method of administration

Apply a thin, even layer two to four times a day. Once the inflammation has subsided the frequency of use may be reduced.

In atopic dermatitis (eczema), a rebound of pre-existing dermatoses can occur with abrupt discontinuation of topical corticosteroid preparations. Therapy with topical corticosteroids should be gradually discontinued once control is achieved and an emollient continued as maintenance therapy.

4.3. Contraindications

DP LOTION-HC 1% is contraindicated when viral, fungal, bacterial or parasitic infections are present at the lesion site. Use is also contraindicated where pruritus is due to psychogenic or internal organ disease, or skin cancer is present. A history of lanolin sensitivity is also a contraindication to use of DP LOTION-HC 1%.

4.4. Special warnings and precautions for use

Although the absorption of hydrocortisone into the systemic circulation is small, the amount absorbed may be increased significantly if prolonged administration occurs or extensive areas are treated. This is particularly so in infants and young children. The use of occlusive dressings may also increase the amount of hydrocortisone reaching the systemic circulation.

Visual disturbance

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

4.5. Interaction with other medicines and other forms of interaction

None known.

4.6. Fertility, pregnancy and lactation

Fertility

No data available.

Pregnancy

The safe use of topical corticosteroids during pregnancy has not been established, therefore, the decision to use either Hydrocortisone preparation to treat a pregnant woman must be decided on the basis of benefit versus potential risk.

Breast-feeding

It is not known whether corticosteroids are distributed into breast milk following topical application. However, topical hydrocortisone should be used in caution in breastfeeding mothers.

4.7. Effects on ability to drive and use machines

None known.

4.8. Undesirable effects

Adverse effects associated with topical application of DP LOTION-HC 1% are unlikely, significant abuse of the product being required. If effects occur, they are likely to be topical such as cutaneous atrophy, petechiae and steroid acne.

Systemic effects may occur when relatively large amounts of hydrocortisone are absorbed. Absorption is influenced by: amount used, duration of treatment and nature of the skin.

Systemic adverse reactions, such as blurred vision, have also been reported with the use of topical corticosteroids (see also section 4.4 Special warnings and precautions for use – Visual Disturbance).

General disorders and administration site conditions

"Rebound effect", see section 4.2.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected reactions https://nzphvc.otago.ac.nz/reporting/

4.9. Overdose

Overdosage may result in cutaneous atrophy, petechiae, steroid acne or systemic effects of glucocorticoid overdose. The preparation should be stopped immediately and the patient monitored for signs of withdrawal and treated appropriately.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Corticosteroids, weak (group I); ATC code: D07A A02

Hydrocortisone is a corticosteroid that, when applied topically, often produces dramatic suppression of lesions having inflammation as a prominent feature. Such lesions include: eczema, various forms of dermatitis, psoriasis and intertrigo. Lanolin is a substance obtained from sheep's wool that, when mixed with mineral oil, gives an emollient lotion that facilitates the absorption of hydrocortisone.

5.2. Pharmacokinetic properties

When applied topically, hydrocortisone is absorbed through the skin allowing penetration to deeper layers. Absorption is aided by the presence of lanolin and mineral oil and also by use of occlusive dressings due to the hydration of the skin layers that results. Very little hydrocortisone reaches the systemic circulation unless the skin is broken or denuded.

5.3. Preclinical safety data

No specific data available.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

DP LOTION-HC 1% contains the following excipients: Cetyl alcohol 95%, Paraffin oil light, Polysorbate 60, Sorbitan monostearate, Liquid lanolin, Propyl paraben, Glycerine, Methyl paraben, Triethanolamine 99% and Water.

6.2. Incompatibilities

None known.

6.3. Shelf life

36 months.

6.4. Special precautions for storage

Store at or below 25°C.

6.5. Nature and contents of container

100mL and 25mL bottle, plastic.

Not all pack sizes may be marketed.

6.6. Special precautions for disposal and other handling

Any unused medicine or waste material should be disposed of in accordance with local requirements.

7. MEDICINE SCHEDULE

Prescription Medicine.

8. SPONSOR

Douglas Pharmaceuticals Ltd
P O Box 45 027
Auckland 0651
New Zealand
Phone: (09) 835 0660

9. DATE OF FIRST APPROVAL

7 December 1989

10.DATE OF REVISION OF THE TEXT

24 February 2022

Summary table of changes

Section Changed	Summary of new information
4.2	Addition of a rebound note as per Medsafe's request
4.6	Rewording of breast-feeding section
4.8	Reference to blurred vision as per section 4.4 added.