

## New Zealand Data Sheet

### 1. PRODUCT NAME

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DP LOTION-HC 1%

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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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

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Uniformly white, glossy, moderately viscous lotion.

### 4. CLINICAL PARTICULARS

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#### **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.

#### **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**

#### **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 sufficient absorption of topical corticosteroids takes place to be excreted in breast milk. The potential benefits should be weighed against possible hazards to the breastfeeding infant.

#### **Fertility**

No data available.

### **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.

## **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**

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#### **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**

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#### **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**

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Prescription medicine.

### **8. SPONSOR**

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

### **9. DATE OF FIRST APPROVAL**

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7 December 1989

### **10. DATE OF REVISION OF THE TEXT**

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12 July 2018

Summary table of changes

<b>Section Changed</b>	<b>Summary of new information</b>
All	SPC format
4.4	Added precaution regarding Visual disturbance, as per Medsafe request