

NEW ZEALAND DATA SHEET

1. PRODUCT NAME (strength pharmaceutical form)

Hydrocortisone Cream 1% (PSM)
Topical Cream
1% w/w

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Name and strength of the active substance

Hydrocortisone Cream 1% (PSM) contains Hydrocortisone 1% w/w

Excipient(s) with known effect

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cream, topical

Presentations

Hydrocortisone Cream 1% (PSM) is a smooth white viscous cream

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

HYDROCORTISONE is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses.

4.2 Dose and method of administration

A thin film should be applied to the affected area three to four times daily.

4.3 Contraindications

HYDROCORTISONE is contraindicated in patients with a history of hypersensitivity to the product or any of its constituent ingredients, patients with tuberculosis or fungal infection and/or herpes infections of the eyes, lips or genitals.

4.4 Special warnings and precautions for use

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

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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.

Although extensive use of HYDROCORTISONE has not revealed evidence that enough HYDROCORTISONE is absorbed to have systemic effects, greater absorption because of misuse or individual variability or unusual sensitivity could lead, at least theoretically, to a systemic effect.

Patients are advised to contact their physician if the condition under treatment worsens or if symptoms persist for more than seven days or if symptoms clear and occur again within a few days.

HYDROCORTISONE is not recommended for use in children under two years of age.

HYDROCORTISONE should not be used for external feminine itching if a vaginal discharge is present. It is not to be used for external anal itching if bleeding is present.

Do not use on the face and avoid contact with the eyes.

If the product is applied with the fingertips, hands should be washed afterwards.

Do not apply to infected skin lesions, including acne.

Do not use under bandages or dressings except on medical advice. Caution: contains chlorocresol as preservative.

For external use only

4.5 Interaction with other medicines and other forms of interaction

There are currently no known drug interactions associations with the topical application of HYDROCORTISONE.

4.6 Fertility, pregnancy and lactation

The safety of this medicinal product for use during human pregnancy or during lactation has not been established.

HYDROCORTISONE should only be used during pregnancy or lactation if recommended by a physician.

4.7 Effects on ability to drive and use machines

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Presumed to be safe or unlikely to produce an effect on the ability to drive or use machinery.

4.8 Undesirable effects

The safety profile of topically applied HYDROCORTISONE preparations has been established through over 40 years of marketing experience. Topically applied HYDROCORTISONE generally does not produce systemic effects due to minimal absorption. Absorption increases in the presence of skin inflammation or with the use of occlusive agents. Certain local effects such as skin atrophy may arise with prolonged use because of the antimitotic/antisyntetic effect of HYDROCORTISONE on cells. Clinically detectable atrophy rarely occurs with HYDROCORTISONE in concentrations available (1.0% w/w, 0.5% w/w).

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 adverse reactions <https://nzphvc.otago.ac.nz/reporting/>

4.9 Overdose

There is no specific overdose syndrome associated with the use of topical HYDROCORTISONE.

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

Actions

HYDROCORTISONE is a corticosteroid.

When applied topically, HYDROCORTISONE diffuses across cell membranes to form complexes with specific cytoplasmic receptors. These complexes enter the cell nucleus, bind to DNA, and stimulate transcription of messenger RNA and subsequent protein synthesis of enzymes responsible for anti-inflammatory effects, including inhibition of edema, fibrin deposition, capillary dilation, and movements of phagocytes. Later states of inflammation such as capillary production, collagen deposition, and keloid formation are also inhibited.

At a concentration of 1%, topically applied HYDROCORTISONE has been found to bring about both subjective and objective improvements, usually within one week and often as soon as 24 to 48 hours after initiation of therapy.

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Systemic effects from prolonged external application of large amounts of HYDROCORTISONE to wide areas of damaged skin have been minimal. Adrenal axis suppression has not been observed. When massive doses of HYDROCORTISONE are applied to diseased skin, changes in some laboratory parameters are observed without any change in the clinical status of the patient.

5.2 Pharmacokinetic properties

Following topical application, HYDROCORTISONE diffuses through the skin by both transfollicular and transepidermal routes. Absorption varies according to anatomic site of application and ranges from 1% (forearm skin) to 26-29% (mucous membranes). Factors influencing penetration include concentration, vehicle, anatomic site, age, condition of the skin, and occlusion. The plasma level of HYDROCORTISONE falls to 50% of its initial concentration in 90 minutes; the biological half-life of HYDROCORTISONE is 8 to 12 hours. Biotransformation takes place primarily in the skin, and for any amount absorbed systemically, in the liver. 0.2% to 1.0% of HYDROCORTISONE appeared in the urine over 10 days after topical application of C14 radio labelled HYDROCORTISONE to normal skin.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to those included in other sections

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetomacrogol 1000
Cetostearyl alcohol
Liquid paraffin
Purified water
White soft paraffin
Chlorocresol as preservative

6.2 Incompatibilities

In the absence of compatibility studies, this medicine must not be mixed with other medicines.

6.3 Shelf life

Shelf life is 36 months from date of manufacture when stored below 25°C

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6.4 Special precautions for storage

Store below 25°C

6.5 Nature and contents of container

100 g tubes and 500 g and 2kg pots

Note: Not all pack types or pack sizes are available

6.6 Special precautions for disposal

None.

7. MEDICINE SCHEDULE

Prescription Medicine

8. SPONSOR

PSM Healthcare Limited, t/a API Consumer Brands
PO Box 76 401
Manukau City
AUCKLAND 2241
Telephone 0508 776746

9. DATE OF FIRST APPROVAL

29/05/1980

10. DATE OF REVISION OF THE TEXT

May 2018

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SUMMARY TABLE OF CHANGES

Section changes	Summary of new information
All sections	Reformat to SPC style as per new datasheet template effective 1/03/2017. Product name for the 1% w/w product corrected. Other minor changes.
All sections	All references to Hydrocortisone BPC Topical Cream 0.5% w/w removed as product is obsolete.
Section 4.4	Visual disturbance precaution added to Section 4.4. Request is a result of Medsafe's investigation of action taken by EMA to update SmPC for corticosteroid containing products.
Section 4.8	'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 adverse reactions https://nzphvc.otago.ac.nz/reporting/ ' included.
Section 4.9	'For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).' Included.