

# NEW ZEALAND DATA SHEET

## HYDROCORTISONE BPC

## HYDROCORTISONE CREAM 1%

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### PRESENTATION

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HYDROCORTISONE BPC, Topical Cream, 0.5%, is a smooth white viscous cream.

HYDROCORTISONE Cream 1%, Topical Cream, is a smooth white viscous cream.

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### USES

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#### ***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.

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.

#### ***Pharmacokinetics***

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 radiolabeled HYDROCORTISONE to normal skin.

### ***Indications***

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

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## **DOSAGE AND ADMINISTRATION**

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

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## **CONTRAINDICATIONS**

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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.

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## **WARNINGS AND PRECAUTIONS**

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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

### **Use in 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.

### **Effects on ability to drive and use machinery**

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

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## **ADVERSE EFFECTS**

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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 (0.5%, 1.0%).

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## **INTERACTIONS**

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

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## **OVERDOSAGE**

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

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**PHARMACEUTICAL PRECAUTIONS**

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Store below 25°C.  
Shelf life is 36 months from date of manufacture

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**MEDICINE CLASSIFICATION**

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HYDROCORTISONE BPC, Topical Cream, 0.5%  
500g pot dispensing pack – Prescription Medicine

HYDROCORTISONE Cream 1%, Topical Cream  
500g and 2kg pot dispensing pack, 100g tube - Prescription Medicine  
15g and 30g tube - Restricted Medicine

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**PACKAGE QUANTITIES**

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HYDROCORTISONE BPC, Topical Cream, 0.5%, is available in a pot of 500g

HYDROCORTISONE Cream 1%, Topical Cream, is available in tubes of 15g, 30g, 100g and pots of 500g and 2kg.

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**FURTHER INFORMATION**

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Also contains:

CETOMACROGOL 1000  
CETO STEARYL ALCOHOL  
LIQUID PARAFFIN  
PURIFIED WATER  
WHITE SOFT PARAFFIN  
CHLOROCRESOL as preservative

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**NAME AND ADDRESS**

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**DATE OF PREPARATION**

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