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PACKAGE LEAFLET: INFORMATION FOR THE USER
HYDROCORTISONE CREAM 1%
Hydrocortisone

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Hydrocortisone Cream is and what it is used for
2. What you need to know before you use Hydrocortisone Cream
3. How to use Hydrocortisone Cream
4. Possible side effects
5. How to store Hydrocortisone Cream
6. Contents of the pack and other information

1. WHAT HYDROCORTISONE CREAM IS AND WHAT IT IS USED FOR

Hydrocortisone belongs to a group of medicines called topical corticosteroids. These work by calming the inflammation that occurs during certain skin conditions or reactions. Hydrocortisone Cream may be used for treating various skin conditions including:

- Eczema
- Dermatitis, including intertrigo (irritation between skin folds)
- Insect bite reactions
- Inflammation of the external ear (otitis external)
- Prurigo nodularis- a long term skin condition where very itchy lumps appear
- Neurodermatoses- a long term skin condition where itchy skin becomes thick due to scratching
- Nappy rash, if infection exists it is being treated with appropriate antibiotics.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE HYDROCORTISONE CREAM

Hydrocortisone 1% is classed as a mild corticosteroid.

Your healthcare professional will prescribe or advise a steroid of the appropriate potency for your condition.

Do not use Hydrocortisone Cream if you:

- Are allergic to hydrocortisone or any of the other ingredients of this medicine (listed in section 6)
- Have any other skin infection such as athlete's foot (tinea pedis), chickenpox (varicella) or shingles (Herpes zoster), coldsores (Herpes simplex), impetigo, ringworm or thrush, infected lesions, ulcerative conditions, red appearance on face, peri-oral dermatitis or acne.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Hydrocortisone Cream if you:

- Have psoriasis, the condition may become worse after stopping long-term treatment
- Will be applying the cream to your face. This cream should not be used for long on the face as it may damage the facial skin
- Are using this cream under occlusive dressing that can considerably increase the absorption of this cream.
- If there is a worsening of your condition during use consult your prescriber- you may be experiencing an allergic reaction, have an infection or your condition requires a different treatment.
- If you experience a recurrence of your condition shortly after stopping treatment, within 2 weeks, do not restart using the cream/ointment without consulting your prescriber unless your prescriber has previously advised you to so.
- If your condition has resolved and on recurrence the redness extends beyond the initial treatment area and you experience a burning sensation, please seek medical advice before restarting treatment.

Caution should be taken to keep away from the eyes. Contact your doctor if you experience blurred vision or other visual disturbances.

Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Children

Talk to your doctor or pharmacist or nurse before using Hydrocortisone Cream if you will be using the cream for the treatment of dermatitis or nappy rash on children and infants. In children and infants treatment should not normally exceed 7 days.

Other medicines and Hydrocortisone Cream

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine. If you are breast-feeding, do not apply the product to your chest area.

Hydrocortisone Cream contains Chlorocresol

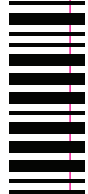
This may cause allergic reactions.

3. HOW TO USE HYDROCORTISONE CREAM

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

For application to the skin.

Wash your hands before and after applying Hydrocortisone Cream, but if applying to the hands, do not wash after application.



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- Apply sufficient cream to thinly cover the affected area and gently rub into the skin until it disappears
- If the affected area becomes weepy or infected, stop using the cream and speak to your doctor. You may need to start antibiotic treatment, especially if the infection spreads
- You should not normally use Hydrocortisone Cream on the face for many weeks or months, unless specifically prescribed by your doctor.

The recommended dose is:

Adults (including the elderly)

- Gently apply a thin layer of cream to the affected area(s) two or three times a day.

Children and Infants

- Apply as for adults but avoid long term use. Treatment should be limited to seven days - especially in infants
- The lowest concentration suitable should be used
- Do not use under a nappy or an airtight dressing (such as a plaster) on an infant because this will enable too much active ingredient to pass through the skin.

If you use more Hydrocortisone Cream than you should

If you squeeze out too much cream, wipe off the excess with a paper towel. Do not use the cream under airtight dressings (such as plasters) or nappies, as too much hydrocortisone may be absorbed and may result in adverse effects upon adrenal gland function.

If you forget to use Hydrocortisone Cream

If you forget to apply the Hydrocortisone Cream, apply it as soon as possible and carry on as before. If it is 3 hours or less until the next application, then ignore the missed dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. Most patients using Hydrocortisone Cream will have no problems when used in the correct amount for the prescribed time.

If the following happens, stop using the cream and tell your doctor immediately or go to the casualty department at your nearest hospital:

- An allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives). This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

Other effects which may occur:

- The skin may become thinner when used in the nappy areas of children where conditions are moist
- If Hydrocortisone Cream is used often over a large area of skin or for a long time, especially under dressings, adverse effects on adrenal gland function are more likely. These effects are also more likely in children and infants
- Prolonged use, especially on sensitive areas including skin folds, may result in thinning of the skin, widening of the blood vessels, stretch marks and may suppress the functioning of the adrenal gland.
- Blurred vision. This side effect has been reported, but the frequency for it to occur is not known.
- Steroid withdrawal reaction: If used over prolonged periods a withdrawal reaction, which might appear to be different from the previous condition, may occur in some patients during treatment or within days to weeks after stopping treatment, with some or all of the following features: redness of the skin which can extend beyond the initial area treated, a burning or stinging sensation, intense itching, peeling of the skin, oozing open sores.

If your condition becomes worse during treatment, you may have an allergy to one of the ingredients of the cream or an infection. Stop using the cream and tell your doctor as soon as possible.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE HYDROCORTISONE CREAM

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date stated on the carton. The expiry date refers to the last day of that month.

Do not store above 25 °C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Hydrocortisone Cream contains

The active substance is micronised hydrocortisone.

The other ingredients are cetomacrogol emulsifying wax, chlorocresol (see section 2), liquid paraffin, macrogol 300, white soft paraffin and purified water.

What Hydrocortisone Cream looks like and contents of the pack

A collapsible aluminium tube, with a membrane seal at the nozzle, internal epoxy lacquer, latex endseal band in the crimp seal area and a white plastic cap for reclosure after piercing membrane.

Hydrocortisone Cream is provided in 15g, 30g and 50g tubes.

Marketing Authorisation Holder

Strides Pharma UK Ltd.,
Unit 4, The Metro Centre
Dwight Road, Watford
WD18 9SS, United Kingdom.

Manufacturer

Beltapharm SpA
Via Stelvio, 66 - 20095 Cusano
Milano - Milan - Italy

This leaflet was last revised in 12/2023.

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Dimensions - 150 x 300 mm

Front Side

Dimensions - 150 x 300 mm

Back side

ARTWORK DETAIL LABEL

Product	Hydrocortisone Cream 1% (Beltapharma)				
Buyer/Country	SPUK	Component	Pack Insert		
Dimension	150 x 300 mm		Pack	30 g	
New Item Code	1049420	Old Item Code	1047862		
Colour Shades	Black		No. of Colours	1	
Change Control No.	PC-TSG/2023/150 - Record Number:395052 / PC-TSG/2023/169 - Record Number:397879			Artwork Version	2.0
Design/Style	Front & Back Printing. To be supplied in folded size of 150 x 150mm				
Substrate	40 GSM Bible Paper				
Special Instructions	Printing clarity to be clear & sharp.				
Autocartanator Requirements	NA				
Prepared By:	Reviewed By:	Approved By:	Approved By:	Authorised By:	
PDC - AW	PDC - Tech	Mkt/BD	RAD	QA	
FOR ARTWORK REVISION PURPOSE					
To be filled by SCM (Planning)		Effective Date:	Sign & Date:		
Caution to the printer: Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.					

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