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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.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

**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 is used for the relief of mild inflammatory skin disorders including:

- mild to moderate eczema
- irritant contact dermatitis or allergic contact dermatitis
- insect bite reactions.

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

Hydrocortisone 1% is classed as a mild corticosteroid.

**Do not use Hydrocortisone Cream:**

- If you are allergic to hydrocortisone or any of the other ingredients of this medicine (listed in section 6).
- On the face, eyes, anus or genital areas.
- If you 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 your condition worsens during use, consult a pharmacist or doctor- 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 a pharmacist or doctor.
- 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**

Do not use for children under 10 years of age without medical advice.

Talk to your doctor, 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 taking this medicine. If you are breast-feeding, do not apply the product to your chest area.

Caution should be exercised when Hydrocortisone Cream is administered to nursing mothers.

**Hydrocortisone Cream contains Chlorocresol**

This may cause allergic reactions.

**3. HOW TO USE HYDROCORTISONE CREAM**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist 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.

- 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) once or twice a day.

**Children and Infants**

- Do not use for children under 10 years of age without medical advice
- 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 or someone else accidentally swallows some cream, contact your doctor or go to your nearest hospital emergency department immediately, take the cream with you so the doctor knows what you have taken.

**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](http://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, 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 10g and 15g tubes. Not all pack sizes may be marketed.

**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  
Milanino - Milan - Italy

This leaflet was last revised in 12/2023.

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PL 13606/0022  
1049419



Dimensions - 150 x 300 mm

Front Side

Dimensions - 150 x 300 mm

Back side

**ARTWORK DETAIL LABEL**

<b>Product</b>	Hydrocortisone Cream 1% (Beltapharma)			
<b>Buyer/Country</b>	SPUK	<b>Component</b>	Pack Insert	
<b>Dimension</b>	150 x 300 mm		<b>Pack</b>	10 & 15g
<b>New Item Code</b>	1049419	<b>Old Item Code</b>	1047819	
<b>Colour Shades</b>	Black		<b>No. of Colours</b>	1
<b>Change Control No.</b>	PC-TSG/2023/150 - Record Number:395052 / PC-TSG/2023/169 - Record Number:397879		<b>Artwork Version</b>	2.0
<b>Design/Style</b>	Front & Back Printing. To be supplied in folded size of 150 x 150mm			
<b>Substrate</b>	40 GSM Bible Paper			
<b>Special Instructions</b>	Printing clarity to be clear & sharp.			
<b>Autocartanator Requirements</b>	NA			
<b>Prepared By:</b>	<b>Reviewed By:</b>	<b>Approved By:</b>	<b>Approved By:</b>	<b>Authorised By:</b>
PDC - AW	PDC - Tech	Mkt/BD	RAD	QA
<b>FOR ARTWORK REVISION PURPOSE</b>				
<b>To be filled by SCM (Planning)</b>	<b>Effective Date:</b>	<b>Sign &amp; Date:</b>		
<b>Caution to the printer:</b> 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. <b>DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.</b>				

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