



PACKAGE LEAFLET: INFORMATION FOR THE USER
HYDROCORTISONE OINTMENT 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, pharmacist or nurse. 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 Ointment is and what it is used for
2. What you need to know before you use Hydrocortisone Ointment
3. How to use Hydrocortisone Ointment
4. Possible side effects
5. How to store Hydrocortisone Ointment
6. Contents of the pack and other information

1. What Hydrocortisone Ointment is and what it is used for

Hydrocortisone Ointment contains the active substance micronised hydrocortisone. Hydrocortisone belongs to a group of medicines called corticosteroids, which act to relieve pain and swelling.

Hydrocortisone Ointment is a topical anti-inflammatory used in the treatment of

- Irritant dermatitis (inflammation of the skin)
- Contact allergic dermatitis
- Insect bite reactions
- Mild to moderate eczema (inflammation of the skin).

2. What you need to know before you use Hydrocortisone Ointment

Hydrocortisone 1% is classed as a mild corticosteroid.

Do not use Hydrocortisone Ointment:

- If you are allergic to hydrocortisone or any of the other ingredients of this medicine (listed in section 6)
- If you have an untreated 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
- On the eyes and face or ano-genital area.

Warnings and precautions

Talk to your doctor or pharmacist before using Hydrocortisone Ointment:

- If you have psoriasis; the condition may become worse after stopping long-term treatment
- If you will be applying the ointment to your face. This ointment should not be used for long on the face as it may damage the facial skin
- If you will be using the ointment for the treatment of dermatitis or nappy rash on children and infants. In this case the courses of treatment should not normally exceed 7 days
- If you are using this ointment under occlusive dressing that can considerably increase absorption of this ointment.
- 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

This product is not recommended for use on children under 10 years of age without medical supervision. Treatment in children should be restricted to no more than 5-7 days.

Other medicines and Hydrocortisone Ointment

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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.

Hydrocortisone Ointment contains wool fat (lanolin)

This may cause local skin reactions (e.g. contact dermatitis).

3. How to use Hydrocortisone Ointment

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

Check with your doctor or pharmacist if you are not sure.

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

- Apply a small amount of ointment and smooth over the affected area



61021

Dimensions - 150 x 300 mm

Front Side

- If the affected area becomes weepy or infected, stop using the ointment and speak to your doctor. You may need to start antibiotic treatment, especially if the infection spreads.
- You should not normally use Hydrocortisone Ointment on the face for many weeks or months, unless specifically prescribed by your doctor.

The recommended dose is:

Adults (including the elderly)

- Gently apply ointment to the affected area(s) once or twice a day, reducing as the skin heals.

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. Follow your doctor's instructions carefully if using to treat nappy rash.

This product is not recommended for use on children under 10 years of age without medical supervision.

If you use more Hydrocortisone Ointment than you should

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

If you forget to use Hydrocortisone Ointment

If you forget to apply the Hydrocortisone Ointment, 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 Ointment will have no problems when used in the correct amount for the prescribed time.

If the following happens, stop using the ointment 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 Ointment is used often and 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 or an infection. Stop using the ointment 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 Ointment

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

Do not use this medicine after the expiry date which is 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 Ointment contains

The active substance is micronised hydrocortisone.

The other ingredients are wool fat (see section 2), liquid paraffin and white soft paraffin.

What Hydrocortisone Ointment 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 Ointment is provided in a 15 g tube.

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.

PL 13606/0189
PL 13606/0187

1049422



02201

Back side

ARTWORK DETAIL LABEL

Product	Hydrocortisone Ointment 1% (Beltapharma)			
Buyer/Country	SPUK	Component	Pack Insert	
Dimension	150 x 300 mm			Pack 15g
New Item Code	1049422	Old Item Code	1047820	
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.				

RD/PD/003/F-01/R0