



PACKAGE LEAFLET: INFORMATION FOR THE USER

Skincalm Bite and Sting Relief 1% Cream 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 has 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 3 days.

What is in this leaflet:

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

1. WHAT SKINCALM BITE AND STING RELIEF 1% CREAM IS AND WHAT IT IS USED FOR

This medicine contains hydrocortisone which belongs to a group of medicines called corticosteroids, which act to relieve pain and swelling. It can be used to relieve the swelling, itching and irritation caused by insect bite and sting reactions.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE SKINCALM BITE AND STING RELIEF 1% CREAM

Do not use Skincalm Bite and Sting Relief 1% 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), cold sores (Herpes simplex), impetigo, ringworm or thrush, infected lesions, ulcerative conditions, red appearance on face, peri-oral dermatitis or acne
- If you are a child under 10 years old
- For other bites and stings or for other skin conditions.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Skincalm Bite and Sting Relief 1% 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.

Children

Do not use for children under 10 years of age.

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

If this product comes into contact with dressings, clothing and bedding, the fabric can be easily ignited with a naked flame. You should keep away from fire when using this product.

Other medicines and Skincalm Bite and Sting Relief 1% 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.

Skincalm Bite and Sting Relief 1% Cream contains Chlorocresol

This may cause allergic reactions.

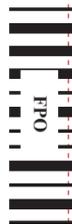
3. HOW TO USE SKINCALM BITE AND STING RELIEF 1% CREAM

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 Skincalm Bite and Sting Relief 1% 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 Skincalm Bite and Sting Relief 1% 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 for no longer than 3 days.

Children aged 10 years and above

- Apply as for adults but avoid long term use. Treatment should be limited to 3 days
- The lowest concentration suitable should be used
- Do not use under a nappy or an airtight dressing (such as a plaster) because this will enable too much active ingredient to pass through the skin.

Do not use for children under 10 years old.

If you use more Skincalm Bite and Sting Relief 1% Cream than you should

Do not use more of this cream than recommended. If you squeeze out too much cream, wipe off the excess with a paper towel. This medicine is for use on the skin only and should not be used in the mouth or swallowed. If it is accidentally swallowed, rinse out the mouth with water and talk to a doctor.

If you forget to use Skincalm Bite and Sting Relief 1% Cream

If you forget to apply Skincalm Bite and Sting Relief 1% 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 Skincalm Bite and Sting Relief 1% 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 Skincalm Bite and Sting Relief 1% 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
- 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.

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 SKINCALM BITE AND STING RELIEF 1% 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 Skincalm Bite and Sting Relief 1% 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 Skincalm Bite and Sting Relief 1% Cream looks like and contents of the pack

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

This medicine is available in a 10g tube.

Marketing Authorisation Holder

Strides Pharma UK Ltd.
Unit 4 Metro Centre, Tolpits Lane,
Watford, Hertfordshire, WD18 9SS.

This leaflet was last revised in 02/2018.

Manufacturer

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



Dimensions - 150 x 300 mm

Front Side

Dimensions - 150 x 300 mm

Back side

Artwork for submission: SPUK

Product Name: Skincalm - Bite and Sting Relief Cream - Pack insert-GSL

Dimension: 150 x 300 mm

Colour: Black