

Package leaflet: Information for the patient
Sovereign Bite and Sting Relief 1% Cream
hydrocortisone acetate

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

- This medicine is available without prescription to treat minor conditions. However, you still need to use it carefully to get the best results from it.
- 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 Sovereign Bite and Sting Relief 1% Cream is and what it is used for**
- 2. What you need to know before you use Sovereign Bite and Sting Relief 1% Cream**
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1. What Sovereign Bite and Sting Relief 1% Cream is and what it is used for

This medicine contains hydrocortisone acetate, which belongs to a group of medicines called corticosteroids or steroids, which act to relieve pain and swelling. It can be used for the treatment of insect bite and sting reactions.

Corticosteroid creams, ointments and other topical preparations come in four different potencies or strengths. These are known as mild, moderately potent, potent or very potent. Healthcare professionals will usually refer to topical corticosteroid potency rather than strength. A potent or strong corticosteroid has a much stronger effect than a mild corticosteroid when using the same amount. Be aware the percentage of active ingredient that is sometimes included on product packaging does not indicate potency. Sovereign Bite and Sting Relief 1% Cream is classed as a mild corticosteroid. Your healthcare professional will prescribe or advise a steroid of the appropriate potency for your condition.

2. What you need to know before you use Sovereign Bite and Sting Relief 1% Cream

This medicine can be used by adults and children of 10 years and over. However, some people should not use this medicine or should seek the advice of their pharmacist or doctor first.

X Do not use:

- **if you are allergic to** hydrocortisone or any of the other ingredients of this medicine (listed in section 6) (allergic reactions include mild symptoms such as itching and/or rash. More severe symptoms include swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing).
- **If you are under 10 years of age**
- **If you have broken or infected skin** – this includes impetigo, cold sores, acne, athlete's foot or an infected bites or stings
- **On the face or eyes** e.g. in rosacea or perioral dermatoses
- **On the anal or genital areas**
- **On bites and stings that are not** caused by insects e.g. animal bites or nettle stings
- **On other skin conditions** such as eczema or dermatitis
- **If you are pregnant or breastfeeding**, unless advised by a doctor
- **For more than 3 days**

! Talk to your pharmacist or doctor:

- **If you experience blurred vision** or other visual disturbances

If there is a worsening of your condition during use, consult your doctor – you may be experiencing an allergic reaction, have an infection, or your condition requires a different treatment.

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.

If you experience a recurrence of your condition, shortly after stopping treatment, within 2 weeks, do not restart using the cream without consulting your doctor or pharmacist. 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.

If you use other medicines

This cream is not expected to cause problems with any other medicine you use.

3. How to use Sovereign Bite and Sting Relief 1% Cream

- Check the tube seal is not broken before first use. If it is, do not use the cream.
- Pierce tube seal with end of cap.
- Apply to the skin only.

Age	How much to use	How often to use it
Adults and children of 10 years and over	A very small amount on the affected area	Once or twice a day for 2 to 3 days

Do not use on children under 10 years.

Do not use more than the amount recommended above.

If your symptoms get worse talk to a pharmacist or doctor.

If your symptoms do not go away within 3 days, talk to a pharmacist or doctor.

This medicine is for use on the skin only and should not be put in the mouth or swallowed. **If it is swallowed** accidentally rinse out the mouth and talk to a doctor.

4. Possible side effects

Most people will not have problems, but some may get some.

If you get any of these side effects, stop using the cream and see a doctor:

- Allergic reactions (e.g. skin rash, red or itchy skin, worsening of the condition you are treating).
- Blurred vision. This side effect has been reported, but it is not known how often.

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.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects 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 Sovereign Bite and Sting Relief 1% Cream

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

Do not store above 25°C.

Use by the date on the end flap of the carton.

Do not use any medicine after the expiry date on the carton and tube and keep them in their original pack.

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 this medicine contains

The active ingredient is hydrocortisone acetate present at a concentration of 1%. The other inactive ingredients are: cetomacrogol emulsifying wax, liquid paraffin, white soft paraffin, chlorocresol and purified water.

What this medicine looks like and the contents of the pack

Sovereign Bite and Sting Relief 1% Cream is a soft, white cream, with a faint characteristic odour.

It is available in a tube containing 10 g of cream.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Sovereign Medical, Sovereign House, Miles Gray Road, Basildon, Essex, SS14 3FR, UK

Manufacturer

Waymade Plc, Sovereign House, Miles Gray Road, Basildon, Essex, SS14 3FR, UK

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