BOOTS BITE AND STING RELIEF HYDROCORTISONE CREAM

(HYDROCORTISONE ACETATE 1% W/W)

PL 00014/0658

UK Public Assessment Report

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BOOTS BITE AND STING RELIEF HYDROCORTISONE CREAM

(HYDROCORTISONE ACETATE 1% W/W)

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LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Crookes Healthcare Limited a Marketing Authorisation (licence) for the medicinal product Boots Bite and Sting Relief Hydrocortisone Cream (PL 00327/0150) on 30th January 2008. This MA underwent Change of Ownership on 6th March 2008, and is now authorised to The Boots Company plc as PL 00014/0658. This is a General Sales List (GSL) medicine.

The application was a reclassification application by which the legal status of the product was changed from pharmacy only supply (P) to supply to the general public (GSL). Concurrently to the reclassification application, the Change of Ownership application (CoA) was processed. The MA, 00014/0658 (The Boots Company plc), was originally submitted and assessed as PL 00327/0150 (Crookes Healthcare Limited).

Boots Bite and Sting Relief Hydrocortisone Cream contains the active ingredient hydrocortisone, which belongs to a group of medicines called corticosteroids. It is used to relieve the swelling, itching and irritation caused by insect bites and stings.

No new or unexpected safety concerns arose from this application and it was therefore judged that the benefits of using Boots Bite and Sting Relief Hydrocortisone Cream outweigh the risk; hence a Marketing Authorisation (MA) has been granted.

BOOTS BITE AND STING RELIEF HYDROCORTISONE CREAM

(HYDROCORTISONE ACETATE 1% W/W)

PL 00014/0658

SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the MHRA granted Crookes Healthcare Limited a Marketing Authorisation for the medicinal product Boots Bite and Sting Relief Hydrocortisone Cream (PL 00327/0150) on 30th January 2008. This MA underwent Change of Ownership on 6th March 2008, and is now authorised to The Boots Company plc as PL 00014/0658. The product is a GSL medicine indicated for the treatment of insect bite and sting reactions.

The application was submitted as a simple abridged application in association with a reclassification application, and cross refers to the approved product, Hc45 Hydrocortisone Cream (PL 00327/0039), a P licence also held by Crookes Healthcare Limited, granted on 7th November 1986.

The Marketing Authorisation application was assessed in parallel with the reclassification application. The approved MA is identical to the reference MA, apart from some differences which relate directly to the reclassification. The reclassification of the product, from P to GSL status has been assessed and deemed satisfactory, following review by the Committee on Safety of Medicines (CSM) and a public consultation exercise. Running concurrently to the reclassification application, a Change of Ownership application (CoA) was granted, and the Marketing Authorisation PL 00327/0150 (Crookes Healthcare Limited) was transferred to PL 00014/0658 (The Boots Company plc) on 6th March 2008.

No new data was submitted nor was it necessary for this simple application, as the data is identical to that of the previously granted cross-reference product.

Boots Bite and Sting Relief Hydrocortisone Cream contains the active ingredient hydrocortisone (as hydrocortisone acetate), which belongs to a group of medicines called corticosteroids. Corticosteroids have anti-inflammatory activity. The cream is used to relieve the swelling, itching and irritation caused by insect bites and stings.

PHARMACEUTICAL ASSESSMENT

LICENCE NO:	PL 00014/0658
PROPRIETARY NAME:	Boots Bite and Sting Relief Hydrocortisone Cream
ACTIVE(S):	Hydrocortisone acetate 1% w/w
COMPANY NAME:	The Boots Company plc
LEGAL STATUS:	GSL

1. INTRODUCTION

This is a reclassification application for general sale availability of hydrocortisone cream, containing hydrocortisone acetate 1%, to be available for the treatment of insect bite and sting reactions for adults and children aged 10 years and over with a maximum pack size of 10g. The proposed name is Boots Bite and Sting Relief Hydrocortisone Cream and the proposed dosage is:

'Apply sparingly to a small area, once or twice a day, for a maximum of 2-3 days.'

The reclassification application is linked to a simple abridged application. The MA application cross refers to the approved product, Hc45 Hydrocortisone Cream (PL 00327/0039), a P licence also held by Crookes Healthcare Limited, granted on 7th November 1986. This cross reference product is indicated for the treatment of irritant contact dermatitis, allergic contact dermatitis, insect bite reactions, and mild to moderate eczema.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 Name(s)

The proposed product name is Boots Bite and Sting Relief Hydrocortisone Cream. The product has been named in line with current requirements and the proposed name is acceptable.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes

Boots Bite and Sting Relief Hydrocortisone Cream contains the active ingredient hydrocortisone, as hydrocortisone acetate 1% w/w. The cream is supplied in aluminium tubes containing 10g.

The proposed shelf-life (3 years) and storage conditions (Do not store above 25°C) are consistent with the details registered for the cross-reference product.

2.3 Legal status

The product is available to the general public, as a GSL medicine.

2.4 Marketing Authorisation holder / Contact Persons / Company

The approved Marketing Authorisation holder is:

The Boots Company plc,
1 Thane Road West,
Nottingham, NG2 3AA

The QP responsible for pharmacovigilance is stated and his CV is included.

2.5 Manufacturers

The proposed manufacturing site is consistent with that registered for the cross-reference product and evidence of GMP compliance has been provided.

2.6 Qualitative and quantitative composition

The proposed composition is consistent with the details registered for the cross-reference product.

2.7 Manufacturing process

The proposed manufacturing process is consistent with the details registered for the cross-reference product and the maximum batch size is stated.

2.8 Finished product / shelf-life specification

The proposed finished product specification is in line with the details registered for the cross-reference product.

2.9 Drug substance specification

The proposed drug substance specification is consistent with the details registered for the cross-reference product.

2.10 TSE Compliance

No materials of animal or human origin are included in the product. This is consistent with the cross reference product.

3. EXPERT REPORTS

Satisfactory expert reports and Curriculum Vitae of experts are provided.

4. PRODUCT NAME & APPEARANCE

See 2.1 for details of the approved product name. The appearance of the product is identical to the cross-reference product.

5. SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

The proposed SmPC is consistent with the details registered for the cross-reference product.

6. PATIENT INFORMATION LEAFLET (PIL) / CARTON

6.1 PIL

The patient information leaflet has been prepared in the user tested format and in line with the SmPC and details registered for the cross-reference product. The approved PIL is satisfactory.

6.2 Carton and blister

The approved artwork is comparable to the artwork registered for the cross-reference product and complies with statutory requirements. In line with current legislation the applicant has also included the name of the product in Braille on the outer packaging and has included sufficient space for a standard UK pharmacy dispensing label.

7. CONCLUSIONS

The data submitted with the application is acceptable. The proposed MA is identical to the reference MA, apart from differences which relate directly to the associated reclassification application.

The grounds for this application are considered adequate. There are no pharmaceutical issues to address. It is recommended that a Marketing Authorisation is granted.

RECLASSIFICATION ASSESSMENT

This is a reclassification application for the general sale availability of Boots Bite and Sting Relief Hydrocortisone Cream, containing hydrocortisone acetate 1% w/w, for the treatment of insect bite and sting reactions for adults and children aged 10 years and over with a maximum pack size of 10g.

Hydrocortisone is currently available as a Pharmacy medicine for use in irritant dermatitis, contact allergic dermatitis, insect bite reactions, and mild to moderate eczema. It is also available without prescription in combination with clotrimazole or miconazole for athlete's foot and candidal intertrigo (sweat rash) or in combination with lignocaine for anal and perianal itch associated with haemorrhoids. Hydrocortisone was first reclassified from POM to P in 1986.

The reclassification of Boots Bite and Sting Relief Hydrocortisone Cream was considered by the CSM in June 2002 and went for subsequent public consultation in August 2002. In November 2002 the CSM considered the responses to consultation and issued its recommendations.

1. CRITERION FOR GSL STATUS

Section 51 of the Medicines Act 1968 states that "GSL status may be appropriate for medicines which can, with reasonable safety be sold or supplied otherwise than by or under the supervision of a pharmacist". "Reasonable safety" may be usefully defined as "Where the hazard to health and the risk of misuse and the need for special precautions in handling are small, and where wider sale would be a convenience to the purchaser".

2. EFFICACY

2.1 Use of hydrocortisone for relief of insect sting reactions

The Expert Report that was submitted by the applicant discussed the efficacy of hydrocortisone acetate 1% in treating insect bite and sting reactions.

2.1.1 Nature of reaction

Insect bite reactions result from substances in the saliva of the biting insect being injected into the skin during feeding, for example the saliva of mosquitoes contains an anticoagulant and antigenic components such as amino acids.

Insect sting reactions result from venom being injected by the insect, in some cases the sting being left in the skin, e.g. bees, when venom continues to be injected.

The content of venoms varies between species but includes antigenic proteins such as hyaluronidase and phospholipase A, histamine, melitin and mast cell degranulating peptide. A majority of patients who have shown local or systemic reactions to insect stings have demonstrable IgE antibody to venom constituents.

Typically a localised reaction ensues consisting of a wheal followed by a persistent papule and erythema and itching. Frequently a central punctum can be seen, the site of penetration of the bite or sting. Occasionally, a more severe local or systemic reaction occurs, particularly with the venom of insect stings, and may result in an anaphylactic reaction.

2.1.2 Use of hydrocortisone to treat insect bite and stings

The company expert has included a comprehensive review of insect sting and bite products. This only refers specifically to hydrocortisone being used to treat insect bite reactions. No references or clinical data have been provided to demonstrate efficacy of topical hydrocortisone in relieving insect sting reactions.

References from standard texts (Goodman and Gilman, Dollery) describe the anti-inflammatory action of hydrocortisone, stating that it is probably mediated by the reduction in formation, release and action of the various vasoactive chemicals released during inflammation such as kinins, histamine, lysosomal enzymes, prostaglandins and the complement system.

An additional reference (Non Prescription Drugs, A. Li Wan Po) refers to inhibition of phospholipase A (found in some venoms) leading to reduced availability of arachidonic acid and inhibition of prostaglandin synthesis.

The expert concludes that because topical hydrocortisone reduces pain, inflammation and itching in insect bite reactions, it appears reasonable to expect similar efficacy in the treatment of insect sting reactions.

2.2 Assessment of Legal Classification

The application is considered with reference to the criteria for GSL legal status (see section 1 above).

2.2.1 Hazard to Health

Hydrocortisone acetate 1% has been available as a Pharmacy medicine since 1985 for the treatment of dermatitis, mild to moderate eczema and insect bite reactions. Restrictions on use include; duration of use not to exceed 7 days, not to be used on the face or anogenital region, and not to be used on children under 10 years of age.

The expert has provided a brief discussion of safety in use. It is noted that no adverse reactions were reported to the applicant following the most recent Periodic Safety Update Report (PSUR). Furthermore, the applicant has received no Adverse Drug Reaction (ADR) reports during the period December 2000 to January 2002.

A Drug Analysis Print for topical hydrocortisone covering the period 9/8/86 to 30/01/02 shows 57 reactions for single constituent hydrocortisone products, most of which were in the skin and subcutaneous tissue disorders system organ class, and consisted of rashes, pruritus and other application site reactions.

From the small number of ADR reports, it can be concluded that safety in use as a Pharmacy medicine has been demonstrated.

2.2.2 Risk of Misuse

Risk of misuse has been considered by the expert, but principally in relation to overuse for the proposed indication.

The proposed indications for the GSL product, namely insect bite and sting reactions, are easy to self diagnose. Insect bites and stings commonly occur on the face as this is a part of the body which is permanently exposed. There is therefore a risk that the product may be used on the face, especially if purchased without professional advice. The expert considers that this would not be a problem if the product is used for only 2-3 days. However, without a pharmacist's advice, it is possible that a patient may continue to treat facial lesions including eczema for a longer period of time.

The name of the product contains the declaration of the active ingredient, which will be familiar to users of topical hydrocortisone. The expert does not consider that there is a risk that patients will use the product to treat other conditions e.g. eczema or even simple dry skin conditions in an unsupervised manner, as the name and product packaging indicate clearly that the product is specifically for treatment of bite and sting reactions.

Topical hydrocortisone has been available for many years through pharmacies and there is no evidence that misuse has occurred, either in relation to application for inappropriate indications or for use on the face or on children.

2.2.3. The need to take special precautions in handling is small

There are no special precautions for handling which would preclude the GSL availability of the Bite and Sting Relief Hydrocortisone cream.

2.2.4. Wider availability would be a convenience to the purchaser

The expert notes that insect bites and stings can occur in any location such as when away from home taking part in leisure activities or on holiday. Therefore, availability in retail outlets including petrol stations and campsite shops would be a convenience, as it is preferable to apply a product as soon as possible after being bitten.

3. ROLE OF THE PHARMACIST

The pharmacist plays an important role in reinforcing labelling instructions, particularly in respect of duration of use and contraindications. In the case of hydrocortisone this includes use on the face and use in children under 10 years of age.

If a patient is purchasing hydrocortisone to treat dermatitis or eczema a pharmacist can discuss the treatment with the patient and if necessary advise that a doctor should be consulted. The pharmacist is also able to advise on which conditions are suitable for treatment with a steroid cream, and therefore avoid inappropriate use of a steroid.

4. PRODUCT INFORMATION

The company expert suggests that there are no safety issues with Boots Bite and Sting Relief Hydrocortisone Cream. However, the proposed product is for general sale without the safety net of a pharmacist to provide professional advice. As a result, the inexperienced product user only has the PIL and carton information with which to ensure the product is used safely and effectively. The indications for the GSL product are more restrictive and it is important that the packaging makes it clear what the product is to be used for and what it should not be used for.

Changes to the product information were made during the course of the application to reflect the GSL use of the product.

4.1 Summary of Product Characteristics (SmPC)

The SmPC was updated in accordance with the CSM advice and recommendations, and reflects the GSL use of the product. The final SmPC is satisfactory.

4.1 Label

The labelling makes it clear what the product is for by 'Bite and Sting Relief' being incorporated into the product name, by the statement of indication, and further by the statement that it should not be used for other bites and stings or for other skin conditions. This helps to ensure correct use of the product when sold without the supervision of a pharmacist.

The approved labelling artwork complies with statutory requirements, and includes the name of the product in Braille.

4.2 Patient Information Leaflet (PIL)

The approved PIL is in line with the final SmPC, is in the user tested format, and is satisfactory.

The PIL makes it clear what the product is to be used for and when it should not be used. A clear statement that the product should not be used for non-insect bites and stings, or for other skin conditions, has been included.

5. DISCUSSION

Topical hydrocortisone has been available for more than 15 years as a Pharmacy treatment for insect bite reactions. However, it has never been indicated for insect sting reactions.

Insect bites and stings are a common occurrence which can readily be diagnosed by a sufferer. The mechanism of insect bite reactions and insect sting reactions may be similar, although insect stings can cause severe local or system reactions for which systemic treatment would be required. No clinical data have been provided by the applicant to demonstrate efficacy of topical hydrocortisone in insect sting reactions.

Nevertheless, it may be considered that topical hydrocortisone is treating an inflammatory response to a noxious stimulus whether an insect bite or sting, and that the inflammatory reaction is the same, regardless of the source of the insult. The anti-inflammatory action of hydrocortisone would be expected to be the same for both insect bite reactions and insect sting reactions. Moreover it should be considered that when being bitten or stung, a victim often does not know what has inflicted the injury; the first they are aware of is the redness, wheal and inflammatory response. Thus, restricting the indication to insect bite reactions alone would not stop anyone using the product for insect stings.

Approval of GSL availability of hydrocortisone cream would result in this product being available from retail outlets. The inclusion of the name of the active ingredient in the product name makes the product recognisable to consumers who had previously used hydrocortisone to treat dermatitis and eczema. There is therefore a risk that the cream could be used to treat eczema in an unsupervised way. The inclusion of 'Bite and Sting Relief' in the product name should prevent this.

There is also a risk that hydrocortisone would be used inappropriately to treat other skin conditions including simple dry skin conditions or skin infections, without a pharmacist to advise on correct use. However, this potential for misuse has been there even as a Pharmacy medicine, but there is no evidence that hydrocortisone has been misused in this way. The clear label statements should ensure that the product is only used for the indication stated.

Restrictions on use of topical hydrocortisone as a Pharmacy medicine, such as not applying it to the face and not using it on children under 10 years of age, may be ignored without professional advice. Insect bites and stings are very likely to occur on the face and / or on small children. However, the instructions on the packaging clearly state that the product should not be used on the face or on children under 10, and there are other GSL medicines available with similar restrictions so this is not setting a precedent.

6. ADVICE SOUGHT

The advice of the CSM was sought on whether Boots Bite and Sting Relief Hydrocortisone Cream is suitable to be available as a GSL product with the following restrictions:-

- For insect bite and sting reactions only
- Pack size: 10g only
- Dosage: To be applied sparingly twice a day
- Maximum duration of use: 2-3 days
- Not to be used on the eyes, face, anogenital area
- Not to be used on broken or infected skin, including scabies and infected bites or stings
- Not to be used on children under 10 years of age.
- For external use only

7. CSM CONSIDERATION

On 27th June 2002, the Committee considered whether the proposed product falls within a description or class specified under Section 51 of the Medicines Act 1968, as being appropriate for supply otherwise than by, or under the supervision of, a pharmacist under the stated restrictions. The CSM issued its advice to the MAH.

8. CONSULTATION

A consultation exercise was implemented from August to September 2002, whereby the proposal for GSL availability of hydrocortisone cream was issued to various advisory bodies, individuals, and organisations.

There were 40 responses, of which 16 had no comments. Of the responses with comments, 4 were in favour or stated that they had no objections, and 20 were not in favour of the reclassification. However, the issues of concern had already considered by the CSM. No new issues were raised during the consultation.

9. CONCLUSION

The CSM met in November 2002 and noted that the issues raised from the consultation exercise had already been considered.

The MA holder has implemented all the CSM recommendations with regards to the reclassification of the proposed product. The proposed reclassification for general sale availability of Boots Bite and Sting Relief Hydrocortisone Cream in packs of 10g is acceptable, under the conditions listed in section 6.

PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with this application and none are required for an application of this type. A preclinical expert report has been written by a suitably qualified person and is satisfactory.

CLINICAL ASSESSMENT

No new clinical data have been supplied with this application and none are required for an application of this type. A clinical expert report has been written by a suitably qualified person and is satisfactory.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The data for this application is consistent with that previously assessed for the cross-reference product and as such has been judged to be satisfactory.

PRECLINICAL

No new preclinical data were submitted and none are required for an application of this type.

EFFICACY

Medicinal products containing hydrocortisone have been available in the UK for much more than ten years. Their use is well established with recognised efficacy and acceptable safety.

This product is identical to the cross-reference product, Hc45 Hydrocortisone Cream (PL 00327/0039), granted to Crookes Healthcare Limited on 7th November 1986

No new or unexpected safety concerns arise from this application.

PRODUCT LITERATURE

The approved SmPC, PIL and labelling are satisfactory and consistent with that for the cross-reference product.

A package leaflet has been submitted to the MHRA along with results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC. The results indicate that the package leaflet is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.

The approved labelling artwork complies with statutory requirements. In line with current legislation, the name of the product in Braille appears on the outer packaging and sufficient space has been included for a standard UK pharmacy dispensing label.

RISK BENEFIT ASSESSMENT

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant’s product is identical to the cross-reference product. Extensive clinical experience with hydrocortisone is considered to have demonstrated the therapeutic value of the active substance. The risk: benefit is, therefore, considered to be positive.

BOOTS BITE AND STING RELIEF HYDROCORTISONE CREAM

(HYDROCORTISONE ACETATE 1% W/W)

PL 00014/0658

STEPS TAKEN FOR ASSESMENT

1 The MHRA received the marketing authorisation application, PL 00327/0150, on 16th July 2002

2 After initial assessment, advice was sought from the Committee on Safety of Medicines (CSM) with regards to the Reclassification application. The Committee met in June 2002 and issued its advice

3 A consultation exercise was implemented in August 2002, and in November 2002 the CSM considered the responses to consultation, and issued further advice

4 Following review of the application the MHRA requested further information relating to the dossier on 8th April 2003, 26th May 2004, 29th November 2005, and 16th August 2007

5 The applicant responded to the MHRA's requests, providing further information for the dossier on 12th November 2003, 17th March 2005, 5th April 2006, and 17th December 2007 respectively

6 Following assessment of the response the MHRA requested further information relating to the quality sections on 19th December 2007

7 The applicant responded to the MHRA's request, providing further information for the quality sections on 30th January 2008

8 The application, PL 00327/0150, was determined on 30th January 2008

9 The Change of Ownership of the MA from PL 00327/0150 to PL 00014/0658 was finalised on 6th March 2008

SUMMARY OF PRODUCT CHARACTERISTICS

The UK Summary of Product Characteristics (SPC) for Boots Bite and Sting Relief Hydrocortisone Cream is as follows:

1 NAME OF THE MEDICINAL PRODUCT

Boots Bite and Sting Relief Hydrocortisone Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Hydrocortisone Acetate BP 1.0% w/w

3 PHARMACEUTICAL FORM

A smooth, white cream

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Insect bite and sting reactions

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

For topical administration

Apply sparingly to a small area, once or twice a day, for a maximum of 2-3 days. Do not use in pregnancy without medical advice or in children under 10.

4.3 CONTRAINDICATIONS

The product should not be used on the eyes or face, the ano-genital area or on broken or infected skin including impetigo, cold sores, acne, athlete's foot, scabies or infected bites or stings.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

The product labelling shall include the following statements:

If the condition does not improve consult your doctor. Do not use on the eyes or face, anal or genital areas or on broken skin or infected skin, e.g. impetigo, cold sores, acne, athlete's foot, scabies or infected bites or stings. Do not use for other bites or stings or for other skin conditions.

4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

None known.

4.6 PREGNANCY AND LACTATION

This product should not be used in pregnancy without medical advice. There is no information about effects on lactation.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

None known.

4.8 UNDESIRABLE EFFECTS

Treatment with hydrocortisone is usually well tolerated but treatment should be stopped if symptoms of hypersensitivity occur.

4.9 OVERDOSE

No special precautions or antidotes are likely to be needed.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Hydrocortisone is a corticosteroid which has anti-inflammatory activity.

5.2 PHARMACOKINETIC PROPERTIES

Not applicable.

5.3 PRECLINICAL SAFETY DATA

There are no preclinical safety data of relevance to the consumer.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

White soft paraffin
Liquid paraffin
Phenoxyethanol
Purified water
Cetomacragol emulsifying wax

6.2 INCOMPATIBILITIES

None known.

6.3 SHELF LIFE

3 years.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Do not store above 25°C.

6.5 NATURE AND CONTENTS OF CONTAINER

Internally lacquered collapsible aluminium membrane-sealed tube with a polypropylene cap.
Pack size is 10g.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

None

7 MARKETING AUTHORISATION HOLDER

The Boots Company PLC
1 Thane Road West
Nottingham
NG2 3AA

8 MARKETING AUTHORISATION NUMBER(S)

PL 00014/0658

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30/01/2008

10 DATE OF REVISION OF THE TEXT

30/01/2008

PATIENT INFORMATION LEAFLET

Information for the user

Bite & Sting Relief Hydrocortisone Cream (Hydrocortisone Acetate)

Read all of this leaflet carefully 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

What this medicine is for

This medicine contains Hydrocortisone Acetate, 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 bites and stings.

Before you use this medicine

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

✗ Do not use:

- **If you are allergic** to hydrocortisone or any of the other ingredients
- **If you are under 10 years of age**
- **If you are pregnant,** unless advised by a doctor
- **If you have broken or infected skin** – this includes impetigo, cold sores, acne, athlete's foot, scabies or an infected bite or sting
- **On the face or eyes**
- **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 use other medicines

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

How to use this medicine

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 only to the skin.

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.

Possible side effects

Most people will not have problems if used as instructed.

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)

If you notice any side effect not listed here, please tell your pharmacist or doctor.

How to store this medicine

Do not store above 25°C.

Keep this medicine in a safe place out of the sight and reach of children, preferably in a locked cupboard.

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

What is in this medicine

This cream contains Hydrocortisone Acetate 1% w/w, which is the active ingredient.

As well as the active ingredient, the cream also contains white soft paraffin, cetomacrogol emulsifying wax, liquid paraffin, phenoxyethanol, purified water.

The pack contains 10 g of white cream.

Who makes this medicine

Manufactured by the Marketing Authorisation holder The Boots Company PLC Nottingham NG2 3AA

Leaflet prepared January 2008

If you would like any further information about this medicine, please contact The Boots Company PLC Nottingham NG2 3AA.

Other formats

To request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only)

Please be ready to give the following information:

Product name: Boots Bite & Sting Relief Hydrocortisone Cream

Reference number: 00014/0658

This is a service provided by the Royal National Institute of the Blind.

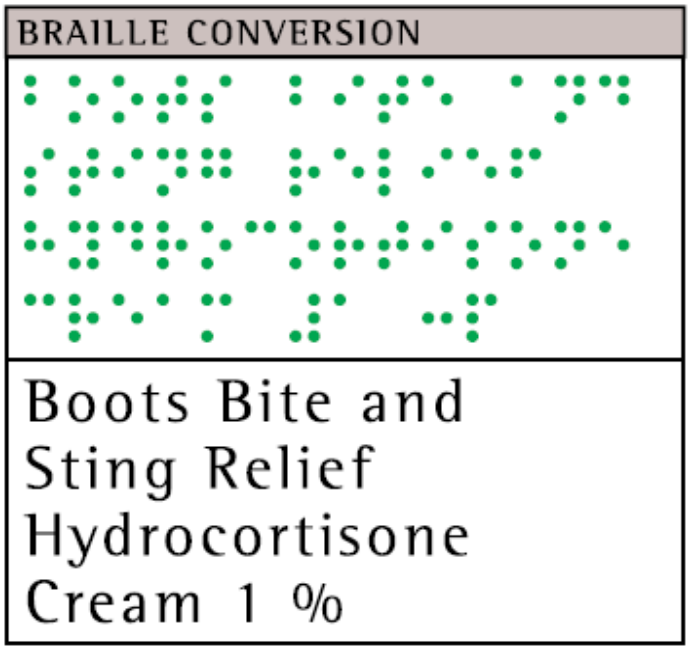
LTSA4

LABELLING

Carton

Carton with Braille

Braille translation



Tube label

Boots
10 g e
Bite & Sting Relief
hydrocortisone Cream
USE BY:
(Hydrocortisone Acetate 1% w/w)
Reduces inflammation, relieves itching and irritation
10 years+
✗Do not use:
• On children under 10 years
• On the face, eyes, anal or genital areas
• On broken or infected skin e.g. impetigo, cold sores, acne, athlete's foot, scabies or infected bites and stings
• For other bites, stings or other skin conditions
• If you are pregnant, unless your doctor tells you to
Directions: Apply to the skin only. Use a small amount only. Apply to the affected area once or twice a day for 2 or 3 days.
If symptoms persist talk to a doctor.
Active ingredient
Hydrocortisone Acetate 1% w/w.
Also contains: white soft paraffin, cetomacrogol emulsifying wax, liquid paraffin, phenoxyethanol, purified water.
Do not store above 25°C.
Keep all medicines out of the sight and reach of children.
LOT:
Use by the date on the tube end.
PL 00014/0658
The Boots Company PLC
Nottingham NG2 3AA