HYDROCORTISONE 1% BITE AND STING RELIEF CREAM

PL 00289/0599

UKPAR

TABLE OF CONTENTS

HYDROCORTISONE 1% BITE AND STING RELIEF CREAM

PL 00289/0599

LAY SUMMARY

The MHRA granted TEVA UK Limited Marketing Authorisation (licence) for the medicinal product Hydrocortisone 1% Bite and Sting Relief Cream (PL 00289/0599).

This is a standard abridged reclassification application submitted by Galpharm under Article 10.c, an informed consent application cross referring to Zenoxone or Hydrocortisone 1% Cream (PL 00018/0033). The applicant has confirmed that this product is pharmaceutically identical to the cross referenced product in terms of qualitative and quantitative composition of active ingredients and excipients. The standard abridged was submitted in association with a reclassification application.

Hydrocortisone 1% Bite and Sting Relief Cream is a general sales list medicine (GSL) medicine used to treat insect bite and sting reactions only in adults and children over 10 years of age. It contains the active ingredient Hydrocortisone, which belongs to a group of medicines called corticosteroids, which are applied to the skin to treat inflammation. Corticosteroids or ‘steroids’ should not be confused with ‘anabolic steroids’.

No new or unexpected safety concerns arose from this application and it was, therefore, judged that the benefits of taking Hydrocortisone 1% bite and sting Relief Cream outweigh the risks, hence Marketing Authorisation has been granted.

HYDROCORTISONE 1% BITE AND STING RELIEF CREAM

PL 00289/0599

SCIENTIFIC DISCUSSION

TABLE OF CONTENTS

INTRODUCTION

The UK granted marketing authorisation for the medicinal product Hydrocortisone 1% bite and sting Relief Cream (PL 000289/0599) to TEVA UK Limited on 20th November 2007. The product is a general sale list medicine (GSL).

The application was submitted as an abridged application according to article 10(c) of Directive 2001/83/EC, cross-referring to hydrocortisone 1% cream (PL 00181/0033) approved on September 1986. The standard abridged was submitted in association with a reclassification application.

Hydrocortisone is a corticosteroid, or 'steroid', which is applied to the skin to treat inflammation, and should not be confused with 'anabolic steroids' or 'sex steroids'. The cream is used to treat insect bite and sting reactions ONLY.

No new data was submitted nor was it necessary for this application, as the data is identical to that of the previously granted cross-reference product. As the cross-reference product was granted prior to the introduction of current legislation, no PAR was generated.

PHARMACEUTICAL ASSESSMENT

1. INTRODUCTION

An application has been received from Galpharm International Limited to reclassify Hydrocortisone 1% cream from Pharmacy (P) to General Sale List (GSL) for the treatment of insect bite and sting reactions in adults, elderly and children above 10 years and above. The reclassification is linked to a standard abridged application submitted by APS Ltd (now TEVA UK Ltd); the reference marketing authorisation is PL 00181/0033 (Hydrocortisone 1% Cream) which has pharmacy (P) legal status.

In June 2002, the CSM considered that hydrocortisone could be sold or supplied as a GSL product, without pharmacist supervision, subject to 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 and stings
- Not to be used on children under 10 years of age

Preclinical, pharmaceutical and clinical expert statements have been provided together with CVs showing the experts are appropriately qualified. The experts confirm that the products are identical in composition, manufacture and pharmaceutical characteristics to the respective reference product and that there are no toxicological or clinical issues.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 Name(s)

The proposed name of the product is Hydrocortisone 1% Bite & Sting Relief Cream.

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

The product contains the active ingredient hydrocortisone 1% w/w. It will be packaged into internally lacquered aluminium tube fitted with a polythene cap with pack size of 10g. The proposed shelf life is 3 years with storage condition “Do not store above 25 degree C”.

2.3 Legal status

The product is General Sale List Medicine(GSL).

2.4 Marketing authorisation holder/Contact Persons/Company

The proposed Marketing Authorisation holder is TEVA UK Limited, Brampton Road, Hampden Park, Eastbourne, East Sussex, BN22 9AG, United Kingdom.

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

2.5 Manufacturers

The proposed manufacturing sites are 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 compositions are consistent with the details registered for the cross-reference products.

2.7 Manufacturing process

The proposed manufacturing process is consistent with the details registered for the cross-reference products 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 products.

2.9 Drug substance specification

The proposed drug substance specification conformed to current Ph Eur monograph for hydrocortisone and was consistent with that of the reference product.

Current Ph Eur certificates of suitability for all three drug substance manufacturer have been provided to support the sources of active substance. These manufacturers are in line with the reference product.

2.10 Bioequivalence / Bioavailability

No bioavailability and bioequivalence data are required to support this informed consent application as the proposed product is manufactured to the same formula utilising the same process. The finished product manufacturing site is also identical to that used by the reference product.

3. EXPERT REPORTS

The applicant has included detailed expert reports of the application. Signed declarations and copies of the experts' CVs are enclosed for the quality, non-clinical and clinical experts. All are considered to have sufficient experience for their responsibilities.

4. PRODUCT NAME & APPEARANCE

See 2.1 for details of the proposed product names. The appearances of the product are identical to the cross-reference products.

5. SUMMARY OF PRODUCT CHARACTERISTICS

The proposed SmPCs are consistent with the details registered for the cross-reference product with the exception of changes requested by committee for safety medicines in 2002.

6. PATIENT INFORMATION LEAFLET/BLISTER

PIL
The patient information leaflet has been prepared in-line with the details registered for the cross-reference products.

The result of user testing has been provided

The proposed artwork complies with the relevant statutory requirements. In line with current legislation the applicant has also included the name of the product in Braille on the outer packaging.

7. CONCLUSIONS

The data submitted with the application is acceptable. Marketing Authorisation should be granted.

RECLASSIFICATION APPLICATION

An expert report of the GSL reclassification for hydrocortisone 1% bite and sting relief cream has been provided. A clinical safety and efficacy summary has also been provided.

The applicant proposes the P to GSL reclassification of hydrocortisone cream for the treatment of insect bite and sting reactions in adults, elderly and children aged 10 years and above. The proposed posology is the external application of a small amount of cream to the area of the skin affected by the bite or sting once or twice daily for a maximum period of 2-3 days. If the condition does not improve, the patient will be instructed to consult their doctor.

Hydrocortisone cream is already available as a P medicine for the treatment of irritant contact dermatitis, allergic contract dermatitis, insect bite reactions and mild to moderate eczema.

In June 2002, the Committee on the Safety of Medicines (CSM) considered that hydrocortisone could be sold or supplied as a GSL product, without pharmacist supervision, subject to 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 and stings
- Not to be used on children under 10 years of age

The applicant has taken account, and included all of the above information as contained in the public domain. Additionally, a full self-supporting reclassification application for GSL availability has been provided.

1. Criterion for GSL status

This application is assessed against the criterion for GSL status which is given in Section 51 of the Medicines Act 1968; this states that GSL may be appropriate for medicines which can with reasonable safety be sold or supplied otherwise than by or under the supervision of a pharmacist.

The term “with reasonable safety” has been defined as: Where the hazard to health, the risk of misuse, or the need to take special precautions in handling is small and where wider sale would be a convenience to the purchaser.

1.2 Hazard to Health

1.2.1 Insect Bites and Stings

Bites
Insects usually bite in order to feed on the patient's blood. The skin is punctured and the insect's saliva is secreted into the dermis. The saliva usually contains enzymes or other agents to facilitate blood flow back through the feeding apparatus. The saliva may also contain local anaesthetic so that the patient is unaware of the bite; allowing the insect to feed without disturbance. The bite causes little injury; it is the antigenic response that causes problems. Legs, hands and other uncovered areas are the most likely areas for bites and stings. Common, biting insects include midges, gnats, fleas, horse flies, bedbugs and ticks

If a person is hypersensitive to a bite, an immediate urticarial wheal is produced via a type I mediated reaction. Itchy papules, vesicles or nodules develop within 48 hours and are mediated by a delayed type IV hypersensitivity reaction. Lesions can become infected through scratching.

Stings
Insect stings are venomous weapons, used to either incapacitate prey or defend the insect in the case of perceived attack. Pain and inflammation are caused by the pharmacologic effects of the sting venom which contain substances such as histamine, various polypeptides, enzymes and apamin. Common UK stinging insects include wasps, bees and hornets. The stinging apparatus usually contains a venom sac which pumps venom into the wound. The effects include an intense burning sensation, pain, erythema and oedema which usually subside within a few hours. Like bites, stings may also become infected. Sensitive individuals may suffer anaphylaxis and required emergency treatment. This type of patient would not derive benefit from topical hydrocortisone and would require urgent systemic treatment.

Although insect stings are not currently indicated in pharmacy licensed hydrocortisone 1% creams, they are commonly used for this purpose; both in clinical practice and OTC. Insect stings are different from bites in that they are weapons which contain venom, rather than being used for feeding purposes. However, their subsequent reactions are similar; urticaria, erythema and histamine release. Without the causative insect being present, distinguishing the two can be difficult, particularly by dermatological presentation alone. Therefore they are often treated in parallel. Products, such as topical antihistamines and anaesthetics treat insect bites and stings concurrently and because appropriate justification was provided by the applicant, the proposal to extend the use of OTC hydrocortisone for the treatment of stings is an acceptable one. This is also in line with CSM advice which stated that GSL hydrocortisone indications must be limited to bite *and sting* reactions.

1.2.2 Safety Profile of Hydrocortisone

The product proposed for GSL purchase consists of a 10 gram tube containing hydrocortisone 1% w/w to be used sparingly once or twice daily for a maximum period of 2 to 3 days.

Hydrocortisone has been used worldwide for almost 50 years and has been available in pharmacies since 1987. Extensive post-marketing experience has confirmed that it is well tolerated and it has been available in other countries without the direct supervision of a pharmacist for over 25 years. Systemic toxicity is unlikely to be seen with topical administration because the percutaneous absorption of a twice daily administration for no more than 3 days would be minimal. In accordance with the CSM recommendations for GSL availability, the proposed pack size is 10gm and limited to 2-3 days usage.

In the UK ADROIT database [July 1963 to January 2006] there were for 64 adverse events reported for topical hydrocortisone, mainly consisting of erythema, rash and pruritis. Usage figures for the UK were 13,881,497 tubes of cream (PSUR January 1999 to 30th July 2003), indicating its existing wide use.

No drug interactions have been identified for topical hydrocortisone.

Acute overdose does not present a risk.

Considering the large patient exposure to hydrocortisone cream and the small number of adverse events, as well as the minimal systemic absorption, the hazard to health is considered small.

1.3 Risk of Abuse or Misuse

Although it is possible that without the supervision of a doctor or pharmacist, hydrocortisone cream could be misused for the treatment of skin conditions in children or used in inappropriate areas of the body such as the face, anogenital region, broken or infected skin, the potential for intentional or unintentional misuse is small. Historically, hydrocortisone has been used in skin lightening products, but the abuse of hydrocortisone does not appear to have increased as a result of wider availability of hydrocortisone through pharmacies and there is no evidence to suggest that further widening of availability would cause a worsening of abuse. High doses of stronger topical corticosteroids are required for prolonged periods before effective pigmentation changes occur. In addition these products usually contain more potent steroids as well as toxins such as mercury. Given the size of the tube and the quantities required for skin lightening, it is unlikely that this product would be abused in this way. The patient information also clearly states that the cream should not be used for longer than 2-3 days and that if the condition does not improve to consult a doctor. The patient information contains thorough instructions regarding use as well as warning the user about the areas of the body where application should be avoided.

There are age restrictions on the use of the current topical hydrocortisone products, limiting the products' to use in adults and children over 10 years of age. This age

restriction will remain on the proposed reclassified GSL product and the appropriate warnings will appear on both label and leaflet. Therefore the risk of misuse is considered to be small.

1.4 Special precautions in handling

The only precaution when using topical hydrocortisone is to ensure it does not inadvertently get into the eyes and should not be applied to face, anogenital region, broken or infected skin. Use in pregnancy and breastfeeding requires additional medical advice before use. The patient information carries instructions to wash hands immediately after using the cream, unless the hands are the target area of application.

The product contains the phenolic antimicrobial preservative chlorocresol which has been known to cause skin reactions and sensitization. Appropriate excipient warnings are included on the patient information leaflet.

1.5 Convenience to the Purchaser

Wider availability of hydrocortisone cream for the treatment of insect bites and stings would provide improved convenience for those individuals suffering from the effects of bites and stings. At times when pharmacies are closed or not accessible, wider availability from alternate outlets would allow for earlier onset of treatment. Early application is likely to bring about faster symptomatic relief.

1.6 Role of the Pharmacist

Provided the product is adequately labelled, there is no reason to believe that Hydrocortisone 1% Bite and Sting Relief cream would present a safety concern if it is available for sale or supply without pharmacist supervision. Bites and stings are both readily diagnosed by the consumer and the additional restrictions on pack size and duration of treatment offer additional reassurance.

3. PRODUCT INFORMATION

The proposed SPC, patient information leaflet (PIL) and label are supplied. Changes to the product information have been made to reflect the non-prescription use of the product. The PIL has been updated in line with the approved SPC.

4. DISCUSSION

Topical hydrocortisone has been used extensively around the world for more than 50 years and has shown to be safe for use by self-selection in pharmacy. Its safety profile has been shown to be predictable with serious adverse events occurring only rarely.

The use of Hydrocortisone 1% Bite and Sting Relief Cream GSL will be limited to relief from bites and stings only and not for the wider ‘P’ indications of eczema, dermatitis or other more serious skin condition. Bites and stings are readily diagnosed by sufferers which do not generally require diagnoses by their pharmacist or doctor. This should reduce the potential for misdiagnosis. The information provided to the

patient clearly states that the cream should not be used for longer than 2-3 days and that if the symptoms get worse, medical advice is to be sought.

Overall, the risk of misuse is, therefore, minimal. The only potential for misuse is the misapplication to areas of the body where there is greater likelihood of percutaneous absorption. However, the associated risks of systemic effects are small due to the short duration of treatment, and appropriate warnings are provided in the labelling and patient information. The quantity available in the 10g tube will further preclude misuse. For the same reasons, inappropriate use in children under 10 does not pose a serious safety risk and Hydrocortisone 1% Bite and Sting Relief Cream will not be recommended for use in children under the age of 10 years.

The product is easy to use and has few precautions apart from restricting application to risk areas of skin. The patient information carries appropriate instruction about washing hands after use. The product can be used safely for the treatment of bites and stings without supervision by a pharmacist, and wider availability of the product would be convenient to the consumer.

5. CONCLUSION

The advice from CSM regarding hydrocortisone P to GSL reclassification, together with the data provided demonstrate that Hydrocortisone 1% Bite and Sting Relief Cream fulfils the criteria for a product which can be sold as a GSL medicine.

PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with this application and none are required for an application of this type.

CLINICAL ASSESSMENT

No new clinical data have been supplied with this application and none are required for an application of this type.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The data for this application is consistent with that previously assessed for the cross-reference product with the exception of changes requested by committee for safety medicines in 2002 and as such has been judged to be satisfactory.

PRECLINICAL

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

EFFICACY

The applicant has confirmed that this product is pharmaceutically identical to the cross referenced product in terms of qualitative and quantitative composition of active ingredients and excipients.

No new or unexpected safety concerns arise from this application.

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

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 ibuprofen is considered to have demonstrated the therapeutic value of the compound. The risk benefit is therefore considered to be positive.

STEPS TAKEN FOR ASSESMENT

1	The MHRA received the marketing authorisation application on 26/08/2003.
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 24/07/2007.
3	Following assessment of the application the MHRA requested further information on 31/07/2007, 17/08/2007, 04/10/2007 05/11/2007.
4	The applicant responded to the MHRA's requests, providing further information on 16/8/2007, 04/10/2007, 31/10/2007 and 15/11/2007.
7	The application was determined on 20/11/2007

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Hydrocortisone 1% Bite and Sting Relief Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Hydrocortisone 1% w/w
For excipients see 6.1.

3 PHARMACEUTICAL FORM

Cream
A smooth white cream

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of insect bite and sting reactions only

4.2 Posology and method of administration

To be applied topically.

Adults and elderly: Apply sparingly to a small area once or twice daily for a maximum period of 2-3 days. If the condition does not improve consult your doctor.

Children aged 10 years and above: As for adults and the elderly. Do not use for children under 10 years old.

4.3 Contraindications

Known sensitivity to the preparation. Hydrocortisone cream should not be used on the eyes, face, and ano-genital region or on broken or infected skin (including scabies and infected bites or stings, cold sores, athlete's foot, acne or chickenpox). Not to be used for other bites or stings or for other skin conditions.
Chlorocresol may cause allergic reactions.

4.4 Special warnings and precautions for use

Contains hydrocortisone. Do not use on the eyes, face or ano-genital region, broken or infected skin including scabies and infected bites and stings. Do not use in pregnancy without medical advice. Do not use on children under 10. Stop treatment if symptoms of hypersensitivity occur. If the condition does not improve after 2-3 days consult a doctor. Not to be used 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

There is inadequate evidence of the safety of topical corticosteroids in human pregnancy. This product should not be used without medical advice. Effects on lactation are unknown.

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 procedures or antidote are likely to be needed.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Hydrocortisone is a mild, topical corticosteroid.

5.2 Pharmacokinetic properties
a) General characteristics and b) Characteristics in patients: No additional data are available.

5.3 Preclinical safety data
There are no pre-clinical data of relevance to the consumer.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
White Soft Paraffin
Cetomacrogol Emulsifying Wax
Liquid Paraffin
Chlorocresol
Purified Water

6.2 Incompatibilities
None known.

6.3 Shelf life
Three years

6.4 Special precautions for storage
Do not store above 25^{o}C.

6.5 Nature and contents of container
Internally lacquered aluminium tube fitted with a polythene cap.
Pack size: 10g.

6.6 Special precautions for disposal
None

7 MARKETING AUTHORISATION HOLDER
TEVA UK Limited
Eastbourne
BN22 9AG
England

8 MARKETING AUTHORISATION NUMBER(S)
PL 00289/0599

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
20/11/2007

10 DATE OF REVISION OF THE TEXT
20/11/2007

PATIENT INFORMATION LEAFLET

HYDROCORTISONE 1%
BITE AND STING RELIEF CREAM

PATIENT INFORMATION LEAFLET

Read this leaflet carefully because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 3 days.

IN THIS LEAFLET:

1 WHAT THIS MEDICINE IS FOR

Hydrocortisone is a corticosteroid, or 'steroid', which is applied to the skin to treat inflammation, and should not be confused with 'anabolic steroids' or 'sex steroids'.
The cream is used to treat insect bite and sting reactions ONLY.

2 BEFORE YOU USE THE MEDICINE

DO NOT use this cream:
- on the face, eyes or around the anus or genitals
- on broken or infected skin (including scabies, infected bites or stings, cold sores, athletes foot, acne or chickenpox)
- for other bites or stings (not from insects) e.g. animal bites or nettle stings
- for other skin conditions e.g. dermatitis or eczema
- **on children under 10 years of age**
- if you are allergic to hydrocortisone or any of the other ingredients listed in section 6 (see also 'Important Information' below)
- if you are pregnant or trying to become pregnant, except on medical advice.

Ask your doctor or pharmacist if the cream is suitable for you:
- if you have had an allergic reaction to other creams or ointments
- if you are breast feeding.

Important information about one of the ingredients
The cream contains Chlorocresol which may cause allergic reactions.

3 HOW TO USE THE MEDICINE

For use on the skin.
Use this cream only as described in this leaflet and on the carton or tube.
Before first use pierce the tube by inverting the cap over the end of the tube and press. Wash your hands before applying the cream.
Wash your hands after applying the cream unless used to treat bites or stings on the hands.

Further information overleaf.

Age	How to use
Adults and children age 10 years and over.	Apply sparingly to a small area once or twice daily to thinly cover the affected area and gently rub into the skin until the cream disappears.
DO NOT use on children under 10 years.	
Use the cream for a maximum period of 3 days. CONSULT YOUR DOCTOR if the condition does not improve or worsens.	

If you apply too much cream wipe off the excess with a paper towel.

4 POSSIBLE SIDE EFFECTS

Most people use hydrocortisone cream without any problems but, like all medicines, it can have side effects.
STOP USING THE CREAM and talk to your doctor as soon as possible if your condition worsens during treatment. You may have an allergy to one of the ingredients of the cream or you may have an infection.
Symptoms of an allergic reaction include:
- itching, skin rash
- swelling of the lips, tongue or throat
- difficulty breathing.

Contact your doctor or go to your nearest hospital casualty department IMMEDIATELY if you think you have an allergic reaction.

5 STORING THE MEDICINE

Do not use after the expiry date shown on the carton or tube.
Do not store above 25°C.
Keep all medicines out of the reach and sight of children.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 FURTHER INFORMATION

What is in this medicine
The active ingredient is: Hydrocortisone 1.0% w/w.
The other ingredients are: Chlorocresol, Cetomacrogol Emulsifying Wax, White Soft Paraffin, Liquid Paraffin and Purified Water.

What this medicine looks like and contents of the pack
Hydrocortisone 1% Bite and Sting Relief Cream is a smooth, white cream.
The tube contains 10g of cream.

Marketing Authorisation Holder and Manufacturer: TEVA UK Limited, Eastbourne BN22 9AG England.

Date of approval: MM/YYYY

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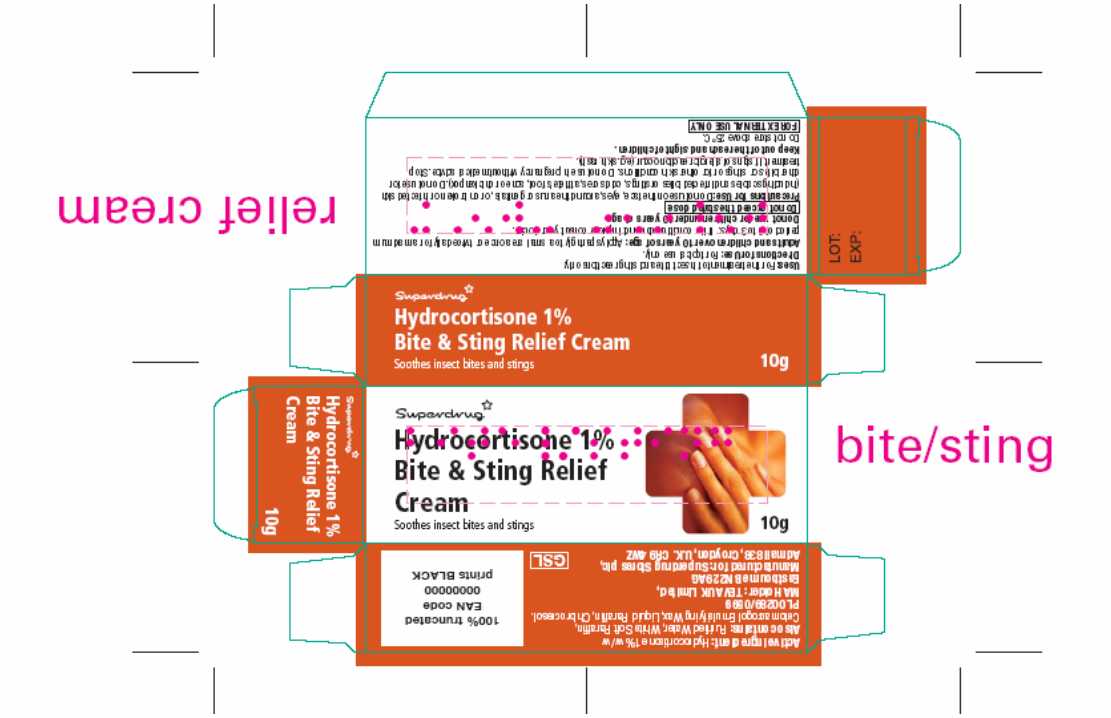
LABELLING

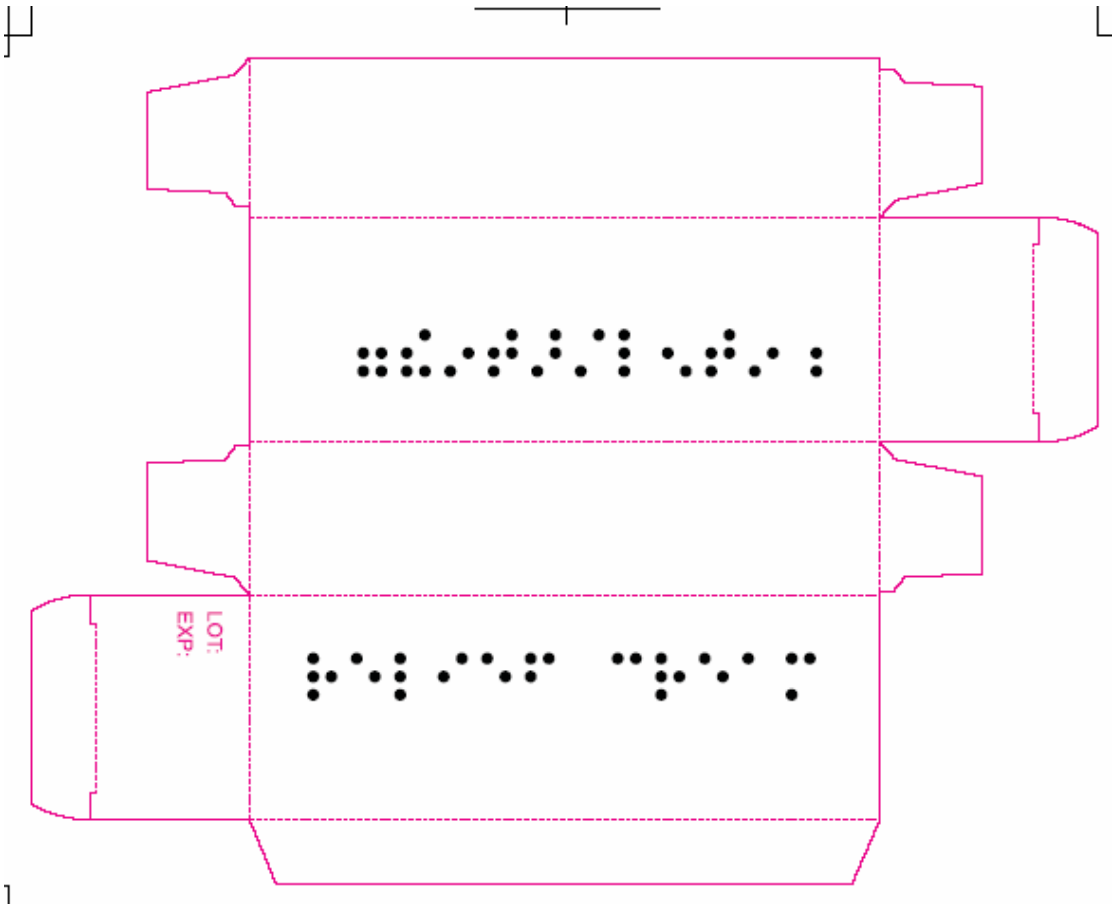

relief cream
galpharm
Hydrocortisone 1%
Bite & Sting Relief Cream
Soothes insect bites and stings
bite/sting
10g
5017353503701


XXXXX-A
galpharm
10g
Hydrocortisone 1%
Bite & Sting Relief Cream
Soothes insect bites and stings
Directions for Use: For topical use.
Adults and children over 10 years of age: Apply sparingly to a small area once or twice daily for a maximum period of 2 to 3 days. If the condition does not improve consult your doctor. Do not use for children under 10 years of age.
Do not exceed the stated dose.
Precautions for Use: Do not use on the face, eyes, around the anus or genitals, or on broken or infected skin (including scabies and infected bites or stings, cold sores, athletes foot, acne or chickenpox). Do not use for other bites or stings or for other skin conditions. Do not use in pregnancy without medical advice. Stop treatment if signs of allergic reaction occur.
Keep out of the reach and sight of children.
Do not store above 25°C.
FOR EXTERNAL USE ONLY
Active Ingredient: Hydrocortisone 1% w/w
GSL
Also contains: Purified Water, White Soft Paraffin, Cetomacrogol Emulsifying Wax, Liquid Paraffin, Chlorocresol.
MA Holder: TEVA UK Limited, Eastbourne, BN22 9AG PL 00289/0599
Distributed By: Galpharm International Ltd., South Yorkshire S75 3SP.


relief cream
Hydrocortisone 1%
Bite & Sting Relief Cream
10g
Soothes insect bites and stings
LOT:
EXP:
bite/sting
GSL
100% truncated
EAN code
0000000
prints BLACK


Dosage
For the treatment of insect bite and sting reactions only. For topical use only.
For external use only.
• Adults and children over 10 years: Apply sparingly to a small area once or twice daily for a maximum period of 2 to 3 days.
If the condition does not improve consult your doctor.
• Do not use for children under 10 years of age.
Do not use
Do not use on the face, eyes, around the anus or genitals, or on broken or infected skin (including scabies and infected bites or stings, cold sores, athlete's foot, acne or chickenpox).
Do not use for other bites or stings or for other skin conditions.
Do not use in pregnancy without medical advice.
GSL
DO NOT EXCEED THE STATED DOSE
WARNINGS
Keep all medicines out of the sight and reach of children.
• Side effects:
Stop treatment if signs of allergic reaction occur (e.g. skin rash).
LOT:
EXP:
TESCO Hydrocortisone 1%
bite & sting relief cream
Soothes insect bites and stings
10g
Ingredients
• Active ingredient: Hydrocortisone 1% w/w. Also contains: Purified Water, White Soft Paraffin, Cetomacrogol Emulsifying Wax, Liquid Paraffin, Chlorocresol.
Storage
• Do not store above 25°C.
Additional information
MA Holder: TEVA UK Limited, Eastbourne, BN22 9AG. PL 00289/0599.
Produced by the Product Licence Holder for Tesco Stores Ltd., Cheshunt EN8 9SL, UK. © Tesco 2006. SC100299.
<0305 0644>


TESCO
Hydrocortisone 1%
bite & sting relief cream
Dosage: For topical use only. For external use only.
• Adults and children over 10 years of age:
Apply sparingly to a small area once or twice daily for a maximum period of 2 to 3 days. If the condition does not improve consult your doctor.
• Do not use for children under 10 years of age.
DO NOT EXCEED THE STATED DOSE
Do not use on the face, eyes, around the anus or genitals, or on broken or infected skin (including scabies and infected bites or stings, cold sores, athlete's foot, acne or chickenpox).
Do not use for other bites or stings or for other skin conditions.
Do not use in pregnancy without medical advice.
WARNINGS: Keep out of the reach and sight of children.
• Stop treatment if signs of allergic reaction occur (e.g. skin rash). Do not store above 25°C.
INGREDIENTS:
• Active ingredient: Hydrocortisone 1 % w/w. Also contains: Purified Water, White Soft Paraffin, Cetostearyl Emulsifying Wax, Liquid Paraffin, Chlorocresol.
MA Holder: TEVA UK Limited, Eastbourne, BN22 9AG. PL 00289/0599. SC100299.
10g
GSL


LOT:
EXP:


Hydrocortisone 1% Bite & Sting Relief Cream
MA Holder: TEVA UK Ltd., Eastbourne BN22 9AG.
PL00289/0599
Manufactured for Sainsbury's Supermarkets Ltd, London EC1N 2HT.
10g e
GSL
Sainsbury's
Hydrocortisone 1% Bite and Sting Relief Cream
10g
Soothes insect bites and stings
Directions: For topical use only.
Adults and children over 10 years of age: Apply sparingly to a small area once or twice daily for a maximum period of 2 to 3 days. If the condition does not improve consult your doctor.
Do not use for children under 10 years of age.
Ingredients: Active ingredient: Hydrocortisone 1% w/w.
Also contains: Purified Water, White Soft Paraffin, Cetomacrogol Emulsifying Wax, Liquid Paraffin, Chlorocresol.
Storage: Do not store above 25°C.
FOR EXTERNAL USE ONLY
Precautions for use:
• Do not use on the face, eyes, around the anus or genitals, or on broken or infected skin (including scabies and infected bites or stings, cold sores, athlete's foot, acne or chicken pox). • Do not use for other bites or stings or for other skin conditions. • Do not use in pregnancy without medical advice. Stop treatment if signs of allergic reaction occur.
• DO NOT EXCEED THE STATED DOSE.
• KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.
LOT:
EXP:


Sainsbury's
Hydrocortisone 1% Bite and Sting Relief Cream
10g e
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MA Holder: TEVA UK Ltd., Eastbourne BN22 9AG.
PL00289/0599
GSL
Manufactured for Sainsbury's Supermarkets Ltd, London EC1N 2HT.
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