GERMOLENE ANTISEPTIC GEL
PL 00010/0306

UKPAR

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LAY SUMMARY

The MHRA granted Bayer plc a Marketing Authorisation (licence) for the medicinal product Germolene Antiseptic Gel (PL 00010/0306) on 07 February 2007. This product is available on the general sales list (GSL) for the treatment of cuts and grazes, insect bites, minor wounds, burns and scalds, and spots.

Germolene Antiseptic Gel contains the active ingredient cetylpyridinium chloride, which is an antiseptic and disinfectant.

This application is a duplicate of a previously granted application for Children's Antiseptic Gel (The Boots Company plc) which had, in turn, been shown to be a generic product of the approved product, First Aid Antiseptic Liquid and, as such, these products can be used interchangeably.

No new or unexpected safety concerns arose from this simple application and it was, therefore, judged that the benefits of using Germolene Antiseptic Gel outweigh the risks, hence a Marketing Authorisation has been granted.

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SCIENTIFIC DISCUSSION

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INTRODUCTION

The UK granted a Marketing Authorisation for the medicinal product Germolene Antiseptic Gel to Bayer plc on 07 February 2007. The product is available on the general sales list.

The application was submitted as a simple abridged application according to article 10c of Directive 2001/83/EC as amended, referring to Children's Antiseptic Gel (The Boots Company plc), approved on 29 October 1996. This standard abridged application had, in turn, been shown to be a generic product of First Aid Antiseptic Liquid, approved on 23 January 1996.

No new data were submitted nor were any necessary for this simple application since the data are identical to that of the previously granted reference product. As the reference product was granted prior to the introduction of current legislation, a Public Assessment Report (PAR) has not been generated for it.

The product contains the active ingredient cetylpyridinium chloride which is a disinfectant with bactericidal activity and is indicated for the treatment of cuts, grazes, insect bites, minor wounds, spots, minor burns and scalds.

PHARMACEUTICAL ASSESSMENT

COMPOSITION

The product is formulated as a gel containing 0.025% w/w of the active pharmaceutical ingredient cetylpyridinium chloride. The excipients present are hypromellose, glycerol, sodium citrate, anhydrous citric acid and purified water.

Germolene Antiseptic Gel is presented in a laminated tube with polythene lined tamper evident seal with a polypropylene cap, laminate tube with polythene ionomer (Surlyn) lined tamper evident seal with a polypropylene cap, or a polythene tube consisting of LLDPE and LDPE with a polypropylene cap.

DRUG SUBSTANCE

Cetylpyridinium chloride

All aspects of the manufacture and control of cetylpyridinium chloride are supported by an EDQM Certificate of Suitability. This certificate is accepted as confirmation of the suitability of cetylpyridinium chloride for inclusion in this medicinal product.

DRUG PRODUCT

Other ingredients

All excipients used in the manufacture of the tablets are routinely tested for compliance with current relevant international standards.

No excipients used contain material of animal or human origin.

Manufacture

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

Finished product specification

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

Stability

Finished product stability data support the proposed shelf-life of 24 months with no special storage conditions.

Bioequivalence/bioavailability

A bioequivalence study was not required for this application.

SPC, PIL and Labels

The SPC and labels are pharmaceutically acceptable.

The product does not have a separate Patient Information Leaflet as the relevant information is detailed on the carton. This is acceptable.

The marketing authorisation holder has provided a commitment to update the Marketing Authorisation with a Patient Information Leaflet/label in compliance with Article 59 of Council Directive 2001/83/EC and that the leaflet/label shall reflect the results of consultation with target patient groups, no later than 01 July 2008.

CONCLUSION

It is recommended that a Marketing Authorisation should be granted for this application.

PRECLINICAL ASSESSMENT

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

CLINICAL ASSESSMENT

As this is a duplicate application for Children's Antiseptic Gel, no new clinical data have been supplied and none are required.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The data for this application are consistent with those previously assessed for the reference product and as such have been judged to be satisfactory.

PRECLINICAL

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

EFFICACY

This application is identical to the previously granted application for Chlidren's Antiseptic Gel in which the applicant provided clinical data.

No new or unexpected safety concerns arise from this application.

The SPC and labelling are satisfactory and consistent with that for the 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 reference product. Clinical experience with cetylpyridinium chloride is considered to have demonstrated the therapeutic value of the compound. The risk benefit is therefore considered to be positive.

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STEPS TAKEN FOR ASSESSMENT

1	The MHRA received the Marketing Authorisation application on 06 December 2004.
2	Following standard checks and communication with the applicant, the MHRA considered the application valid on 10 January 2005.
3	Following assessment of the application, the MHRA requested further information on 04 February 2005 and 28 July 2005.
4	The applicant responded to the MHRA's requests, providing further information on 07 June 2005, 24 January 2006 and 19 December 2006.
5	The application was determined on 07 February 2007.

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STEPS TAKEN AFTER AUTHORISATION - SUMMARY

Date submitted	Application type	Scope	Outcome

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Germolene Antiseptic Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Cetylpyridinium chloride 0.025% w/w

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Gel

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For cuts, grazes, insect bites, minor wounds, spots, minor burns and scalds.

4.2 Posology and method of administration

Adults and children: Apply to the affected area two or three times a day.

For cutaneous use.

4.3 Contraindications

Hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Prolonged and repeated application is inadvisable as hypersensitivity may occur.

Do not use if the skin is weeping or badly inflamed.

Avoid contact with the eyes.

For external use only.

Keep out of the reach and sight of children.

4.5 Interaction with other medicinal products and other forms of interaction

There are no clinically significant interactions.

4.6 Pregnancy and lactation

The safety of Germolene Antiseptic Gel during pregnancy and lactation has not been established but is not considered to constitute a hazard during these periods.

4.7 Effects on ability to drive and use machines

No adverse effects known.

4.8 Undesirable effects

Skin irritation may occasionally occur and hypersensitivity reactions may develop in certain individuals.

4.9 Overdose

It is unlikely that systemic toxicity will result from the ingestion of Germolene Antiseptic Gel, although it may give rise to nausea, vomiting and diarrhoea. Treatment should be symptomatic.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Cetylpyridinium chloride is a quaternary ammonium disinfectant having bactericidal activity against both Gram-positive and Gram-negative organisms.

ATC code: D08AJ03

5.2 Pharmacokinetic properties

None stated.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hypromellose
Glycerol
Sodium citrate
Anhydrous citric acid
Purified water

6.2 Incompatibilities

None stated.

6.3 Shelf life

24 months

6.4 Special precautions for storage

None

6.5 Nature and contents of container

Laminated tube with polythene lined tamper evident seal, fitted with a PP cap or a laminate tube with polythene ionomer (Surlyn) lined tamper evident seal fitted with a PP cap or a polythene tube consisting of LLDPE and LDPE fitted with a PP cap.

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Bayer plc
Bayer House
Strawberry Hill
Newbury RG 14 1JA

Trading as Bayer plc, Consumer Care Division

8 MARKETING AUTHORISATION NUMBER(S)

PL 00010/0306

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

07/02/2007

10 DATE OF REVISION OF THE TEXT

07/02/2007

PATIENT INFORMATION LEAFLET/LABELLING


Germolene®
antiseptic gel (cetylpyridinium chloride 0.025% w/w)
✓ disinfects ✓ helps prevent infection ✓ fragrance free
for all the family
USE BY:
BN:
Uses: Cuts and grazes, insect bites, minor wounds, burns and scalds, and spots.
Directions
Apply to the affected area of skin two or three times a day. If the wound does not appear to heal, talk to your doctor. Do not use if the skin is weeping or badly inflamed. Avoid contact with eyes. Do not use repeatedly or for long periods or over large areas of the skin.
PL Holder: Bayer plc, Consumer Care Division, Newbury, RG14 1JA, U.K.
For external use only.
Keep out of the reach and sight of children.
Active ingredient:
Cetylpyridinium chloride 0.025% w/w.
Also contains: Purified water, glycerol, hypromellose, sodium citrate, citric acid.
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