PHENOL AND CHLORHEXIDINE DIGLUCONATE ANTISEPTIC
CUTANEOUS SPRAY
PL 31308/0037

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PL 31308/0037

LAY SUMMARY

On 22\textsuperscript{nd} November 2011, the MHRA granted Max Remedies Limited a Marketing Authorisation (licence) for Phenol and Chlorhexidine Digluconate Antiseptic Cutaneous Spray.

Phenol and Chlorhexidine Digluconate Antiseptic Cutaneous Spray contains the active ingredients phenol and chlorhexidine digluconate.

Phenol and chlorhexidine digluconate have antiseptic and cleaning properties for the disinfection of skin, wounds and burns. Phenol also has a local anaesthetic action for the relief of pain.

Phenol and Chlorhexidine Digluconate Antiseptic Cutaneous Spray is used to ease pain and help prevent infections from minor cuts and grazes, minor burns, scalds, blisters, stings and insect bites, spots and chapped or rough skin.

No new or unexpected safety concerns arose from this application and it was, therefore, judged that the benefits of taking Phenol and Chlorhexidine Digluconate Antiseptic Cutaneous Spray outweigh the risks; hence a Marketing Authorisation has been granted.
PHENOL AND CHLORHEXIDINE DIGLUCONATE ANTISEPTIC CUTANEOUS SPRAY
PL 31308/0037

SCIENTIFIC DISCUSSION

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Clinical assessment (including statistical assessment) Page 9
Overall conclusions and risk benefit assessment Page 10
INTRODUCTION

The MHRA granted a Marketing Authorisation for the medicinal product Phenol and Chlorhexidine Digluconate Antiseptic Cutaneous Spray (PL 31308/0037) to Max Remedies Limited on 22nd November 2011. This medicine has a general sales licence (GSL) and is an antiseptic and cleansing agent (to help prevent secondary infection) and local anaesthetic for symptomatic relief of:

- minor cuts and grazes,
- minor burns and scalds and blisters,
- stings and insect bites,
- spots and other minor skin disorders.

This application for Phenol and Chlorhexidine Digluconate Antiseptic Cutaneous Spray is submitted according to Article 10c (informed consent applications) of Directive 2001/83/EC, as amended, cross-referring to Germolene Antiseptic Liquid, which was first licensed to Beecham Group PLC on 25th October 1989 (PL 00079/0261). This licence has undergone two changes of ownership, first to Bayer PLC on 1st July 2000 (PL 00010/0261) and then to Max Remedies Limited as Germolene Antiseptic First Aid Wash on 31st July 2008 (PL 31308/0027).

It is considered that the pharmacovigilance system as described by the applicant fulfils the requirements and provides adequate evidence that the applicant has the services of a qualified person responsible for pharmacovigilance together with the necessary means for notification of any adverse reaction suspected of occurring.

A satisfactory justification was provided for the absence of a Risk Management Plan (RMP).

No new data were submitted nor were they necessary for this “simple” application, as the data are identical to that of the previously granted cross-reference product.
PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 31308/0037
PROPRIETARY NAME: Phenol and Chlorhexidine Digluconate Antiseptic Cutaneous Spray
ACTIVE(S): Phenol
Chlorhexidine digluconate
COMPANY NAME: Max Remedies Limited
E.C. ARTICLE: Article 10c of Directive 2001/83/EC, as amended
LEGAL STATUS: General Sales Licence (GSL)

1. INTRODUCTION
This is a “simple” application for Phenol and Chlorhexidine Digluconate Antiseptic Cutaneous Spray (PL 31308/0037) submitted under Article 10c of Directive 2001/83/EC, as amended. The proposed Marketing Authorisation Holder (MAH) is Max Remedies Limited, Stoney Gate House, 2 Greenfield Road, Holmfirth, West Yorkshire, HD9 2JT.

This application cross-refers to Germolene Antiseptic First Aid Wash, which was first licensed as Germolene Antiseptic Liquid to Beecham Group PLC on 25th October 1989 (PL 00079/0261). This licence has undergone two changes of ownership, first to Bayer PLC on 1st July 2000 (PL 00010/0261) and then to Max Remedies Limited as Germolene Antiseptic First Aid Wash on 31st July 2008 (PL 31308/0027).

2. MARKETING AUTHORISATION APPLICATION FORM
2.1 NAME(S)
The name of the product at the present time is Phenol and Chlorhexidine Digluconate Antiseptic Cutaneous Spray. The product name is only temporary as the name does not meet with current guidelines. The MAH have provided a commitment to amend the name with new mock-ups of the PIL and labelling for review to the regulatory authority before marketing the product.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes
Each product contains 1.20% w/v phenol and 1.33% w/v chlorhexidine digluconate (20%) solution (equivalent to chlorhexidine digluconate 0.25% w/v).

The finished product is packaged in clear, straight-sided, oval, polyvinyl chloride (PVC) bottles with a PVC pump spray. Each bottle may be contained in a boxboard carton.
Pack sizes are 50 ml, 100 ml, 150 ml and 200 ml.

The proposed shelf-life is 36 months with no special storage conditions. This is consistent with the details registered for the cross-reference product.

2.3 Legal status
General Sales Licence (GSL).

2.4 Marketing authorisation holder/Contact Persons/Company
Max Remedies Limited, Stoney Gate House, 2 Greenfield Road, Holmfirth, West Yorkshire, HD9 2JT.
The QP responsible for pharmacovigilance is stated and his CV is included.
2.5 Manufacturers
The manufacturing sites are consistent with those registered for the cross-reference product and evidence of GMP compliance has been provided.

2.6 Qualitative and quantitative composition
The composition is consistent with the details registered for the cross-reference product.

2.7 Manufacturing process
The manufacturing process is consistent with the details registered for the cross-reference product.

2.8 Finished product/shelf-life specification
The finished product specification is in-line with the details registered for the cross-reference product.

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

2.10 TSE Compliance
None of the excipients used contain material of animal or human origin. This information is consistent with the cross-reference product.

3. EXPERT REPORTS
Signed declarations and copies of the experts’ CVs are enclosed in Module 1.4 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 name. The appearance of the product is identical to the cross-reference product.

5. SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)
The SmPC is consistent with the details registered for the cross-reference product.

6. PATIENT INFORMATION LEAFLET (PIL)/LABELLING
User testing results have been provided for the PIL for the approved cross-reference product, Germolene Antiseptic First Aid Wash along with a satisfactory bridging report.

The results of consultations with target patient groups ("user testing") are 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 they contain.
Labelling
The 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 included the name of the product in Braille on the packaging and has included sufficient space for a standard UK pharmacy dispensing label.

7. CONCLUSIONS
The data submitted with the application are acceptable. The grant of a Marketing Authorisation is recommended.
NON-CLINICAL ASSESSMENT

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

An Environmental Risk Assessment has not been provided and is not 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 are consistent with those previously approved for the cross-reference product and, as such, has been judged to be satisfactory.

NON-CLINICAL
No new non-clinical data were submitted and none are required for an application of this type.

EFFICACY
This application is identical to the previously granted application, Germolene Antiseptic First Aid Wash, which was first licensed as Germolene Antiseptic Liquid to Beecham Group PLC on 25th October 1989 (PL 00079/0261). This licence has undergone two changes of ownership, first to Bayer PLC on 1st July 2000 (PL 00010/0261) and then to Max Remedies Limited as Germolene Antiseptic First Aid Wash on 31st July 2008 (PL 31308/0027).

No new or unexpected safety concerns arise from this application.

The SmPC, 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 non-clinical or clinical safety concerns have been identified. The applicant’s product is identical to the cross-reference product. Extensive clinical experience with phenol and chlorhexidine digluconate is considered to have demonstrated the therapeutic value of the compound. The risk:benefit is, therefore, considered to be positive.
## STEPS TAKEN FOR ASSESMENT

<table>
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<tr>
<td>1</td>
<td>The MHRA received the Marketing Authorisation Application on 18(^{th}) February 2011.</td>
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<td>2</td>
<td>Following standard checks and communication with the applicant the MHRA considered the application valid on 24(^{th}) February 2011.</td>
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<td>3</td>
<td>Following assessment of the application further information was requested regarding the quality section of the dossier on 28(^{th}) February 2011, 13(^{th}) April 2011, 4(^{th}) August 2011 and 25(^{th}) October 2011.</td>
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<td>4</td>
<td>The applicant responded to the MHRA’s requests, providing further information on 12(^{th}) March 2011, 14(^{th}) July 2011, 6(^{th}) October 2011 and 3(^{rd}) November 2011 for the quality section.</td>
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<td>The application was determined on 22(^{nd}) November 2011.</td>
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PHENOL AND CHLORHEXIDINE DIGLUCONATE ANTISEPTIC CUTANEOUS SPRAY
PL 31308/0037

STEPS TAKEN AFTER ASSESSMENT

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<th>Application type</th>
<th>Scope</th>
<th>Outcome</th>
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SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Phenol and Chlorhexidine Digluconate Antiseptic Cutaneous Spray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Phenol 1.20% w/v
Chlorhexidine digluconate (20%) solution 1.33% w/v
(equivalent to chlorhexidine digluconate 0.25% w/v)

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM
Cutaneous spray, solution (Cutaneous Spray).
A clear, pale pink liquid with a characteristic odour.

4 CLINICAL PARTICULARS
4.1 THERAPEUTIC INDICATIONS
An antiseptic and cleansing agent (to help prevent secondary infection) and local anaesthetic for symptomatic relief of minor cuts and grazes, minor burns and scalds and blisters, stings and insect bites, spots and other minor skin disorders.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION
Route of administration: Cutaneous Use - external application to the skin.
All age groups: Use undiluted. Spray onto the affected area to wash away debris and dirt. If necessary use cotton wool or a clean tissue to remove dirt and excess liquid. Repeat procedure if necessary.

4.3 CONTRAINDICATIONS
Known hypersensitivity to any of the constituents.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE
If symptoms persist or if skin irritation occurs, stop using and consult your doctor.
Keep out of the reach and sight of children.
For external use only.
Keep away from eyes, ears and mouth.
If you accidentally spray this product in your eye, wash thoroughly with water.
Consult a doctor promptly if contact is made with eyes or if product is swallowed.
Do not use as a mouth wash or gargle.

4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION
None stated.

4.6 FERTILITY, PREGNANCY AND LACTATION
Pregnancy
The product is not contra-indicated during pregnancy. However, as with all medicines, caution should be exercised when prescribing to pregnant women.

Lactation
Phenol and chlorhexidine digluconate is not excreted in breast milk. Antiseptic Cutaneous Spray can be used during lactation.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES
None stated.

4.8 UNDESIRABLE EFFECTS
ADR are rare. The most commonly reported are skin and sub-cutaneous tissue disorders: local irritation, rashes and other skin reactions. These are usually mild and disappear if treatment is discontinued.
4.9 **OVERDOSE**

**Repeated topical application**
Frequently repeated topical application on the same site could theoretically lead to skin irritation. However, since the product is only intended for minor skin trauma, extensive exposure is unlikely.

**Accidental or deliberate oral ingestion**
The product would only be expected to be harmful if orally ingested in very large quantities. This is unlikely due to the unpleasant taste of the product. In such a case, the primary concern would be the phenol intake which can cause nausea, vomiting, diarrhoea, headache and, in large amounts, excitement of respiratory stimulation leading to drowsiness and coma. The lethal dose of phenol has been estimated to be 15 grams.

**Treatment**
Gastric lavage with water and charcoal. Administration of demulcents such as egg white or milk and supportive measures.

5 **PHARMACOLOGICAL PROPERTIES**

5.1 **PHARMACODYNAMIC PROPERTIES**
Pharmacotherapeutic Group (ATC Codes):
- D08AC52 (antiseptics and disinfectants: chlorhexidine, combinations)
- D08AE03 (antiseptics and disinfectants: phenol and derivatives)

Phenol - antiseptic and local anaesthetic.
Chlorhexidine digluconate - antiseptic.

5.2 **PHARMACOKINETIC PROPERTIES**
Not applicable.

5.3 **PRECLINICAL SAFETY DATA**
There are no preclinical data of relevance to the prescriber, which are additional to those already included in other sections of the SPC.

6 **PHARMACEUTICAL PARTICULARS**

6.1 **LIST OF EXCIPIENTS**
- Cocamidopropylamine oxide solution (30%)
- Denatured ethanol B
- Perfume Medic 9884
- Denatonium solution (0.25%)
- Ponceau 4R (E124)
- Purified water

6.2 **INCOMPATIBILITIES**
Chlorhexidine is incompatible with anionic agents

6.3 **SHELF LIFE**
36 months

6.4 **SPECIAL PRECAUTIONS FOR STORAGE**
This medicinal product does not require any special storage conditions.

6.5 **NATURE AND CONTENTS OF CONTAINER**
A clear, straight-sided, oval, PVC bottle with a PVC pump spray, containing 50, 100, 150 or 200 ml. Each bottle may be contained in a boxboard carton.

6.6 **SPECIAL PRECAUTIONS FOR DISPOSAL**
No special requirements.

7 **MARKETING AUTHORISATION HOLDER**
Max Remedies Limited
Stoney Gate House
2 Greenfield Road
Holmfirth
West Yorkshire
HD9 2JT

8 MARKETING AUTHORISATION NUMBER(S)
PL 31308/0037

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
22/11/2011

10 DATE OF REVISION OF THE TEXT
22/11/2011
PATIENT INFORMATION LEAFLET

Information for the user
PHENOL AND CHLORHEXIDINE DIGLUCONATE ANTISEPTIC CUTANEOUS SPRAY

Read this leaflet carefully because it contains important information for you. This medicine is available without prescription. However, you still need to use Phenol and Chlorhexidine Digluconate Antiseptic Cutaneous Spray 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.
- You must contact a doctor if your symptoms worsen or do not improve.
- If you have any unusual effects after using this product, tell your doctor or pharmacist.

IN THIS LEAFLET:
1. What is Phenol and Chlorhexidine Digluconate Antiseptic Cutaneous Spray and what is it used for?
4. Possible side effects.
6. Further information.

1. What is Phenol and Chlorhexidine Digluconate Antiseptic Cutaneous Spray and what is it used for?
Phenol and Chlorhexidine Digluconate Antiseptic Cutaneous Spray is used to ease pain and help prevent infections from minor cuts and grazes, minor burns, scalds, blisters, stings and insect bites, spots and chapped or rough skin. The spray contains two active substances, phenol and chlorhexidine digluconate.

2. Before you use Phenol and Chlorhexidine Digluconate Antiseptic Cutaneous Spray
DO NOT use Phenol and Chlorhexidine Digluconate Antiseptic Cutaneous Spray:
- If you have an allergy (hypersensitivity) to phenol or chlorhexidine digluconate or any of the other ingredients of Phenol and Chlorhexidine Digluconate Antiseptic Cutaneous Spray (See section 6, Further Information).

Pregnancy and breast-feeding:
You may use the spray if you are pregnant or breast-feeding but as with all medicines at this time, you should discuss it with your doctor first.

3. How to use Phenol and Chlorhexidine Digluconate Antiseptic Cutaneous Spray
Follow the directions below carefully. Before using the product for the first time, check that the bottle seal is not broken.

Adults and children:
1. Spray onto the affected area of skin to wash away any dirt and debris.
2. If necessary use cotton wool or a clean tissue to remove any remaining dirt and excess liquid.
3. Repeat this procedure until the wound is clean. Do not use with soap.

If your condition does not improve, or a skin irritation or rash does not occur, stop using and consult a pharmacist or doctor.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

This spray is for external use only.
Avoid contact with your eyes, ears and mouth and do not use as a mouthwash or gargle.
If you accidentally spray this product in your eye, wash thoroughly with lots of water and tell your doctor straight away or contact your nearest Accident and Emergency Department.

4. Possible side effects
Like all medicines, Phenol and Chlorhexidine Digluconate Antiseptic Cutaneous Spray can cause side effects, although not everybody gets them.
Rarely, you may experience irritation, rash or other skin reactions at the site of application after applying the spray. Frequent application of the spray to the same area for long periods of time or over large areas of skin may lead to skin irritation.
If you are concerned about this, or if the spray affects you in any other way, stop using Phenol and Chlorhexidine Digluconate Antiseptic Cutaneous Spray and tell your doctor or pharmacist immediately.

5. How to store Phenol and Chlorhexidine Digluconate Antiseptic Cutaneous Spray
Keep out of the reach and sight of children.
The product should be stored in its original carton.
Do not use Phenol and Chlorhexidine Digluconate Antiseptic Cutaneous Spray after the expiry date which is stated on the end flap of the carton and the side of the bottle (marked 'EXP'). The expiry date refers to the last date of that month. 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 Phenol and Chlorhexidine Digluconate Antiseptic Cutaneous Spray contains:
The active substances are phenol 1.2% w/w and chlorhexidine digluconate 0.25% w/w.
The other ingredients are alcohol, cocamidopropylammonium oxide, denatonium, perfume, colour (ponceau 4R (E124)) and water.
What Phenol and Chlorhexidine Digluconate Antiseptic Cutaneous Spray looks like and contents of the pack:
Phenol and Chlorhexidine Digluconate Antiseptic Cutaneous Spray is available in bottles containing 50ml, 100ml, 150ml or 200ml of a clear pale pink liquid with a characteristic odour (not all pack sizes may be marketed).
Distributed by: Chefaro UK Ltd., 4th Floor, Hamilton House, Matleden Place, Bloomsbury, London, WC1H 9BB, UK.
Email: enquiries@chefaro.co.uk
Marketing Authorisation Holder: Max Remedies Ltd., Stoney Gate House, 2 Greenfield Road, Holmfirth, West Yorkshire HD9 2JF, UK.
Manufacturer: Bell, Sons & Co., (Druggists) Ltd., Slaidburn Crescent, Southport, PR9 9AL, UK.
Leaflet revised July 2011.
Remember: if you have any doubt about using Phenol and Chlorhexidine Digluconate Antiseptic Cutaneous Spray correctly, seek the advice of your doctor or pharmacist.
If you would like any further information about this product, please contact: Chefaro UK Ltd., 4th Floor, Hamilton House, Matleden Place, Bloomsbury, London, WC1H 9BB, UK.
Email: enquiries@chefaro.co.uk
LABELLING

The labelling below is the label mock-up for the 100ml pack size. The marketing authorisation holder has stated that it is not intending to market the 50ml, 150ml and 200ml pack sizes at this time; therefore no labelling mock-ups have been submitted. The marketing authorisation holder has committed to submit the UK labelling for the 50ml, 150ml and 200ml pack sizes for review to the regulatory authority before marketing the 50ml, 150ml and 200ml pack sizes.

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Phenol and Chlorhexidine Digluconate Antiseptic Cutaneous Spray

Phenol & Chlorhexidine Digluconate

FOR EXTERNAL USE ONLY

Keep all medicines out of the sight and reach of children.
Use by date on the base of carton and bottle label.

Active Ingredients:
The active substances are phenol 1.2% w/v and chlorhexidine digluconate 0.25% w/v. The other ingredients are alcohol, cocamidopropylamine oxide, danonatium, perfume, colour (ponceau 4R (E124)) and water.

How to store this medicine
The product should be stored in its original carton.

Distributed by:
Chefaro UK Ltd., 4th Floor, Hamilton House, Mabledon Place, Bloomsbury, London, WC1H 9BB, UK.
Email: enquiries@chefaro.co.uk
PL 31308/0037
Max Remedies Ltd., Holmfirth, HD9 2JT
Lot:
EXP:

Phenol and Chlorhexidine Digluconate Antiseptic Cutaneous Spray

Phenol & Chlorhexidine Digluconate

ANAESTHETIC TO SOOTHE ANTISEPTIC TO DISINFECT

For cuts & grazes, minor burns, wounds & skin infections, bites & stings, spots & blisters

100ml