IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PPA1447/048/001
Case No: 2068999

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

G & A Licensing Ltd

Ballymurray, **Co. Roscommon**, **Ireland**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Germolene First Aid 1.2% w/w / 0.25 % w/w Cream

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **16/10/2009**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Germolene First Aid 1.2% w/w / 0.25 % w/w Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Phenol 1.20% w/w and Chlorhexidine Digluconate Solution to give Chlorhexidine Digluconate 0.25% w/w

Also contains cetostearyl alcohol.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream

Product imported from the UK:
A pink, viscous, homogeneous cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the treatment of minor skin irritations.

4.2 Posology and method of administration

Apply as necessary after cleansing for up to 3 days.

4.3 Contraindications

Known hypersensitivity to any of the constituents.

4.4 Special warnings and precautions for use

If symptoms persist or the condition worsens, consult your doctor.

4.5 Interaction with other medicinal products and other forms of interaction

Chlorhexidine is incompatible with anionic agents.

4.6 Pregnancy and lactation

Although use of this product is not contraindicated during pregnancy and lactation, as with all medicines during pregnancy, caution should be exercised.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Rarely irritancy, rashes and other skin conditions may occur.

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 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 and headache.

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

Phenol: Antiseptic and local anaesthetic.

Chlorhexidine gluconate: Antiseptic.

5.2 Pharmacokinetic properties

The product has a local action with minimal risk of systemic effects.

5.3 Preclinical safety data

Preclinical safety data on these active ingredients in the literature, have not revealed any pertinent and conclusive findings which are of relevance to the recommended dosage and use of the product.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetostearyl alcohol
Light liquid paraffin
Polyoxyethylene-(21)-stearyl ether
Polyoxyethylene-(2)-stearyl ether
Dimeticone
Methyl Salicylate
Sunset yellow (E110)
Ponceau (E124)
Purified water

6.2 Incompatibilities

Chlorhexidine is incompatible with anionic agents.

6.3 Shelf Life

The shelf life expiry date of this product is the date shown on the tube and outer carton of the product as marketed in the country of origin.

6.4 Special precautions for storage

Do not store above 25’C.

6.5 Nature and contents of container

30g aluminium tube with a polypropylene cap contained in an overlabelled carton.

6.6 Special precautions for disposal and other handling

No Special requirements.

7 Parallel Product Authorisation Holder

G & A Licensing Ltd
Ballymurray
Co. Roscommon
Ireland

8 Parallel Product Authorisation Number

PPA 1447/48/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16th October 2009

10 DATE OF REVISION OF THE TEXT