

IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PPA1447/049/001

Case No: 2069001

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

Savlon Antiseptic 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 **08/01/2010**.

Signed on behalf of the Irish Medicines Board this

A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Savlon Antiseptic Cream.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients:

Cetrimide	0.50% w/w
Chlorhexidine Gluconate	0.10% w/w

Excipients:

Cetostearyl alcohol
Methyl hydroxybenzoate E218
Propyl hydroxybenzoate E216

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Cream

Imported from United Kingdom

Smooth, white, homogenous cream with an antiseptic odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For prevention and management of superficial infections in skin tissue including wounds and minor burns.

4.2 Posology and method of administration

For cutaneous use.

Apply to the affected area after cleansing.

4.3 Contraindications

Keep out of the eyes and ears.

Use in patients hypersensitive to chlorhexidine.

4.4 Special warnings and precautions for use

If no improvement occurs, or condition worsens, discontinue use and consult doctor.

For external use only.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

No known restriction.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

None known.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Chlorhexidine is an effective antiseptic with a wide range of activity against micro organisms, including gram positive and gram negative bacteria, fungi and viruses.

Cetrimide is a quaternary ammonium compound with surfactant and antiseptic properties.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetostearyl alcohol
Liquid paraffin
Methyl hydroxybenzoate
Propyl hydroxybenzoate
Antiseptic Perfume Compound P2419
Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

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

6.4 Special precautions for storage

Do not store above 30°C

6.5 Nature and contents of container

30g tube with plastic cap in an over labeled outer container.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 Parallel Product Authorisation Holder

G&A Licensing Limited
Ballymurray
Co.Roscommon
Ireland

8 Parallel Product Authorisation Number

PPA1447/49/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th January 2010

10 DATE OF REVISION OF THE TEXT