Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Sterets Chlorasol

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sterets Chlorasol sachets contain:

0.3% w/v available chlorine as sodium hydrochloride solution.

For excipients see 6.1.

3 PHARMACEUTICAL FORM

Topical solution.

A clear colourless sterile solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For topical use only, as determined by the physician.

Sodium hypochlorite is a broad-spectrum anti-microbial agent, effective against bacteria, bacteriophages, spores, yeasts and viruses. Solutions of hypochlorite also have the ability to lyse necrotic tissue.

Chlorasol may be used for the cleansing and desloughing of venous stasis ulcers, pressure ulcers and other cutaneous ulcers.

It is recommended that Chlorasol be used only until clean, healthy granulation tissue has developed and that its use be discontinued after this time.

4.2 Posology and method of adminstration

To be used as directed by the physician.

4.3 Contraindications

Not to be taken internally.
Use in patients with hypersensitivity to the active ingredient.

4.4 Special warnings and special precautions for use

Any portion of the contents of the sachet remaining after use should be discarded.
Keep out of reach of children.
Irritant to the eye and other tissue; following accidental exposure irrigate immediately with copious water or normal saline.

Avoid contact with clothing. In the event of any complications seek medical advice as soon as possible. It is recommended that Chlorasol use be discontinued once healthy granulation tissue has developed. Idiosyncratic skin reactions may occur occasionally.
The sachet should not be used if damaged before opening.

4.5 Interaction with other medicinal products and other forms of interaction

Keep away from strong acids or chlorine gas may be evolved.

4.6 Pregnancy and lactation

Not known.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Localised irritation may occur, can be reduced by protecting surrounding skin with soft paraffin. Discontinue use if irritation prolonged or severe. It is recommended that Chlorasol use be discontinued once healthy granulation tissue has developed.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Chlorasol – (available chlorine)

Bactericidal, sporicidal, fungicidal, protozoacidal and virucidal.
Inactivated by organic matter.
Lyses and deodorises necrotic tissue.

5.2 Pharmacokinetic properties

Because Chlorasol is only used topically and is rapidly inactivated by organic matter, there is no systemic absorption.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified Water

6.2 Incompatibilities

Keep away from strong acids or chlorine gas may be evolved.

6.3 Shelf Life

18 months.

For single use only – Discard any unused solution.

6.4 Special precautions for storage

Do not store above 25°C. Do not freeze. Store out of direct sunlight/ store sachets in outer container.

Once the outer wrapping has been removed sachets should be used within one week.

6.5 Nature and contents of container

Coloured flexible plastic sachets of cast ethylene/propylene co-polymer incorporating a tear notch and bar seal for ease of pouring containing either 25ml or 100ml of solution.

6.6 Instructions for use and handling

None.

7 MARKETING AUTHORISATION HOLDER

Seton Prebbles Ltd
Tubiton House
Oldham
OL1 3HS
UK

8 MARKETING AUTHORISATION NUMBER

PA 483/6/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27th November 1991
Date of last renewal: 27th November 2001

10 DATE OF REVISION OF THE TEXT

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