

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Stiefel Acne Soap

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sulphonated surfactant blend 6.37% w/w.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Soap
An off-white oval-shaped, firm textured soap bar.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As a detergent soap for cleansing of the skin in greasy and hyperkeratotic skin conditions, including acne vulgaris.

4.2 Posology and method of administration

Make a lather with warm water and massage into the affected skin using the finger tips or a facecloth. Rinse and repeat as necessary.

4.3 Contraindications

None.

4.4 Special warnings and precautions for use

None.

4.5 Interaction with other medicinal products and other forms of interaction

None.

4.6 Pregnancy and lactation

There are no restrictions on the use of the product during pregnancy or lactation.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

None.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Stiefel Acne Soap is a detergent bar, comprising a blend of saponified high molecular weight fatty acids with unsaponified sulphonated surfactant blend, which removes grease without irritating the skin. Stiefel Acne Soap provides efficient cleansing in the management of acne and other skin conditions characterised by excess lipids, follicular keratosis and degradation of the sebum.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Soap pellets
N-hydroxyethyl ethylenediamine triacetate solution (Hampol 120)

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

No special precautions for storage.

6.5 Nature and contents of container

100g soap bars, wrapped in polyethylene film and supplied in a unit carton.

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 MARKETING AUTHORISATION HOLDER

Stiefel Laboratories (UK) Ltd
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8 MARKETING AUTHORISATION NUMBER

PA 144/27/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1984

Date of last renewal: 01 October 2004

10 DATE OF REVISION OF THE TEXT

June 2006