Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Aknemycin Ointment, 2 % w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Erythromycin 2% w/w.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Ointment
A whitish coloured ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

The management of acne vulgaris particularly of the papular or pustular type.

4.2 Posology and method of administration

Adults and the Elderly: Apply sparingly to the affected area once or twice daily after thorough cleansing.

Children: Not recommended.

4.3 Contraindications

Hypersensitivity to any of the constituents.

4.4 Special warnings and precautions for use

Prolonged use of anti-infective may result in superinfection due to micro-organisms resistant to that anti-infective.
If there is no response within 6-8 weeks alternative measures should be considered.
Prolonged use is not recommended. A course should not normally exceed 6 months.

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant use with other topical treatment should only be carried out with caution in view of possible cumulative local adverse effects.

4.6 Pregnancy and lactation

Studies of use during pregnancy have not been conducted no statements on safety can be made.
It is recommended that the preparation should only be used with caution in lactating women who are breast feeding, and on areas away from the chest.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Local irritation, erythema and dryness may occur. Diarrhoea has been reported rarely.

4.9 Overdose

Unlikely as the amount of erythromycin is too small to induce systemic toxicity.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Erythromycin acts as a bacteriostat on all pathogens that play a role in acne, in particular on Propionibacterium acnes (Corynebacterium acnes). It inhibits lipolysis of sebum lipids. A direct anti-inflammatory effect is presumed. *In vitro* tests demonstrate a significant reduction in Propionibacterium acnes and micrococcaceae, as well as total pathogens.

5.2 Pharmacokinetic properties

Percutaneous absorption of the active is negligible following topical application of the product to large areas for several weeks. Erythromycin penetrates the sebaceous gland opening where it has been shown to have a bacteriostatic effect.

5.3 Preclinical safety data

There are no data from preclinical studies which provide any information which is in addition to the known effects of erythromycin in humans.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Titanium dioxide
Talc
White soft paraffin
Hard paraffin
Light liquid paraffin
Oleic acid oleyl ester
Cetylstearyl alcohol
Cetylstearyl polyglycol phosphate
Lauryl polyglycol phosphate
Sorbitol
Perfume oil
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

Unopened: 3 years.
Use within 6 months after first opening.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Aluminium tube, with HDPE screw cap, containing 25 g.

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

For external use only.

Avoid contact with eyes.

7 MARKETING AUTHORISATION HOLDER

Crookes Healthcare Limited
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8 MARKETING AUTHORISATION NUMBER

PA 43/33/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21 February 1992

Date of last renewal: 21 February 2002

10 DATE OF REVISION OF THE TEXT

July 2003