Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Cuplex Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Salicylic Acid	11.0	% w/w
Lactic Acid	4.0	% w/w

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Gel

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the topical treatment of common, juvenile, plantar and mosaic warts; corns and callouses.

4.2 Posology and method of administration

Adults (including the elderly) and children:

1. Every night soak the wart in hot water for 5 minutes.
2. Dry thoroughly.
3. Apply one or two drops of Cuplex Gel to the wart and allow to spread.
4. In the morning, remove elastic film and re-apply.
5. Twice, or three times per week, rub away the wart surface carefully (excessive rubbing will cause stinging when Cuplex Gel is applied) with an emery board or pumice stone, then apply Cuplex gel.

Suitable for all ages except in infants.

4.3 Contraindications

Do not apply to facial or anogenital warts. Avoid contact with the eyes. Only apply to the affected area. Keep away from naked flames.

4.4 Special warnings and precautions for use

Warts are contagious and any person suffering from warts should always use their own towel.

Most warts will disappear after 6-12 weeks of treatment with Cuplex Gel, providing instructions are carefully and consistently followed. Where, however, the wart continues to increase in size after 6 weeks treatment, and the patient has not consulted a doctor, the patient should be advised to do so.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

No effects on pregnancy and lactation are anticipated.

4.7 Effects on ability to drive and use machines

No effects are anticipated in the ability to drive and to use machinery.

4.8 Undesirable effects

None expected.

4.9 Overdose

None expected.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The active ingredients present in Cuplex gel have no significant systemic effects. There is a long history of safe use of these active ingredients in the local treatment of warts.

5.2 Pharmacokinetic properties

Salicylic Acid is absorbed percutaneously in varying amounts dependant on several factors, e.g. Vehicle, dosage, skin area, skin conditions etc.

Cuplex is used only on very limited skin areas since corns and callouses are skin diseases of a very limited extension. The amount of Cuplex applied will thus amount to a max. 0.5-1.0g, corresponding to 0.06-0.1g salicylic acid applied once or twice daily. Usually the amount is even smaller. Assuming 100% absorption, the amount of salicylic acid absorbed will be so small that detectable plasma concentrations can hardly be found.

5.3 Preclinical safety data

Nothing relevant to add to the prescribing information.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Venice turpentine
Colophony 63 NORD
Collodion
Ethanol

6.2 Incompatibilities

None known.

6.3 Shelf Life

2 years.

6.4 Special precautions for storage

Do not store above 25ºC. Do not freeze.

6.5 Nature and contents of container

5 gram aluminium tube.

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

Avoid naked flames.

7 MARKETING AUTHORISATION HOLDER

Smith & Nephew Pharmaceuticals Ltd.
Hessle Road
Hull HU3 2BN
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 710/2/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation**:** 30 September 1986

Date of last renewal: 30 September 2001

10 DATE OF REVISION OF THE TEXT

September 2001