SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Cuplex Verruca Gel

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For a full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Topical Gel

A clear yellow-brown viscous gel.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

For the topical treatment of calluses, corns, verrucas and warts.

4.2 Posology and method of administration

For topical administration only.

For adults, the elderly and children over 2 years.

Children under 12 should be treated under adult supervision and treatment of infants less than 2 years is not recommended.

Cuplex Verruca Gel should be applied once daily. The gel should be applied to the callus, corn, verruca and wart every night. Treatment can take up to twelve (12) weeks for resistant lesions to disappear, and it is necessary to persevere with the treatment.
Adults, (including the elderly) and Children (over 2 years):

1. Every night soak the affected site in warm water for 2 to 3 minutes.
2. Dry thoroughly with the patient’s own towel; this towel should be used for the affected site(s) only.
3. Carefully apply one or two drops of Cuplex Verruca Gel to the affected site and allow to dry over the surface. Take care to avoid spreading on to surrounding normal skin. No adhesive plaster is required.
4. The following evening carefully remove and discard the elastic film formed from the previous application. Repeat steps 1 to 3 to re-apply the gel. Hands should be washed after touching the affected site. Occasionally, if removal of the elastic film proves difficult, carefully reapply the gel over it and allow it to dry. This should help thicken the film to assist removal. If necessary, such re-application may be made on two or three successive days.
5. Once a week, rub away the treated surface carefully (excessive rubbing will cause stinging when Cuplex Verruca Gel is applied) with an emery board or pumice stone, then apply Cuplex Verruca Gel.
6. The callus, corn, verruca and wart may take up to twelve (12) weeks to disappear and it is important to persevere with the treatment.
7. If the callus, corn, verruca or wart gets worse or has not disappeared after about 12 weeks of treatment, further advice should be sought from a doctor or pharmacist.
8. At the end of treatment, if the elastic film is difficult to remove, it may be allowed to remain on the skin until it sheds.

4.3 Contraindications

Use of Cuplex Verruca Gel is contraindicated in patients known to be sensitive to salicylic acid, lactic acid or any other ingredients of Cuplex Verruca Gel.

Do not apply to or near to the face, intertriginous or anogenital regions of the body. Not to be used by diabetics or individuals with impaired peripheral blood circulation.

Not to be used on moles, birthmarks, hairy warts or on any other skin lesions for which Cuplex Verruca Gel is not indicated.

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 Verruca 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.

Caution in using this product should be exercised by patients with a peripheral sensory neuropathy or sensory impairment, such as cerebrovascular disease.
Discontinue use if excessive irritation or other unwanted effects occur.

4.5. Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

There is a limited amount of data from the use of salicylic acid and lactic acid in pregnant and breast feeding women.

Salicylic acid and lactic acid have been widely used in this and similar preparations for many years.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Cuplex Verruca Gel may cause irritation in certain patients, which in rare instances may appear as a temporary blemish on the skin. See also section “Special Warnings and Precautions for Use”.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Healthcare professionals are asked to report any suspected adverse reactions via www.mhra.gov.uk/yellowcard.

4.9 Overdose

Any excessive use of Cuplex Verruca Gel may cause irritation of the skin. If this occurs, Cuplex Verucca Gel should be used more sparingly or applied less frequently.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
The active ingredients present in Cuplex Verruca 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

Cuplex Verruca Gel contains 11% salicylic acid and 4% lactic acid in an evaporative collodion-like gel which forms a cohesive and adhesive film on the skin.

The film-forming characteristics of the collodion-like gel vehicle also offer distinct advantages in clinical usage. The gel quickly forms a surface film, well before it dries completely, thereby prolonging the period during which the keratolytic solution can properly infiltrate and achieve intimate contact with the surface layers of the thickened stratum corneum.

Furthermore, even when the film appears to have dried completely, the inclusion of the non-evaporative lactic acid ensures that a proportion of the salicylic acid remains in solution within the vehicle, thus permitting continued release of the keratolytic, which may otherwise be entrapped within the collodion-like film.

Systemic absorption of salicylic acid or lactic acid after application of the recommended daily dose of one or two drops of the preparation to small, circumscribed areas is exceedingly unlikely.

5.3 Preclinical safety data

Nothing relevant to add to the prescribing information

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Venice Turpentine
Colophony
Collodion
Ethanol (96%)

6.2 Incompatibilities

None known
6.3 Shelf life

24 months

6.4 Special precautions for storage

Highly flammable, keep away from naked flames.

Do not Store above 25 °C. Do not freeze.

6.5 Nature and contents of container

Cuplex Verruca Gel is packaged in 5g collapsible aluminium tube.

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Crawford Healthcare Limited
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King Edward Road,
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8 MARKETING AUTHORISATION NUMBER(S)

PL 20074/0001

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