

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Compound W Liquid Wart Remover

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Salicylic Acid 17.0 % w/w.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Cutaneous Solution.

Faintly yellow viscous cutaneous solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As a keratolytic for treatment of warts and verrucae

4.2 Posology and method of administration

Adults and children over 6 years of age:

Gently rub the hard skin from the surface of the wart with a pumice stone or emery board. Apply to wart one drop at a time with dropper-rod until wart is covered. Allow to dry completely. Avoid surrounding skin. Repeat application daily, with regular washing, for up to four weeks.

4.3 Contraindications

Do not use Compound W Liquid Wart Remover on moles, birth marks, genital or facial warts.

Not to be used on children under 6 years except on medical advice.

4.4 Special warnings and precautions for use

If there is doubt as to the diagnosis consult the doctor.

Patients with diabetes should consult their doctor about foot problems.

Avoid contact with the eyes, mouth or mucous membranes.

Do not apply to healthy skin or skin which is inflamed or broken. If Compound W Liquid Wart Remover touches healthy skin, wash off immediately with plenty of water.

If there is no improvement, or aggravation of the condition, the doctor should be consulted.

Flammable product: Keep away from naked flames.

For external use only

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

4.6 Pregnancy and lactation

No contraindications known.

4.7 Effects on ability to drive and use machines

None stated

4.8 Undesirable effects

None known

4.9 Overdose

None probable

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Salicylic acid facilitates desquamation by solubilising the intercellular cement that binds scales in the stratum corneum thereby loosening the keratin.

5.2 Pharmacokinetic properties

Salicylic acid can be absorbed through the skin. It is excreted unchanged in the urine.

5.3 Preclinical safety data

Not applicable

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Acetone
Industrial Methylated Spirits 99%
Procylin (Nitrocellulose DHM 10/25)
Castor Oil

6.2 Incompatibilities

None known.

6.3 Shelf Life

The shelf life expiry date of this product shall not exceed 5 years from the date of its manufacture.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Glass bottle with screw threaded plastic cap and plastic applicator containing 6.5 ml of product.

6.6 Special precautions for disposal and other handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Seton Products Ltd.,
Tubiton House,
Oldham OL1 3HS,
United Kingdom.

8 MARKETING AUTHORISATION NUMBER

PA 0618/043/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1983

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10 DATE OF REVISION OF THE TEXT