

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Freezone Liquid Corn Remover

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The liquid contains 17.00 % w/w of salicylic acid in a formulation as described in the application.

For excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous Liquid
Orange/yellow viscous liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As a keratolytic for treatment of corns.

4.2 Posology and method of administration

Adults and children over the age of six years: Soak the affected foot in warm water for 15 minutes. Dry thoroughly and rub the corn very gently with a pumice store to remove any dead skin. Apply Freezone a drop at a time until the corn is covered.

Apply twice daily for 2-3 days. Repeat if necessary.

4.3 Contraindications

None stated.

4.4 Special warnings and precautions for use

1. If there is doubt as to the diagnosis, consult the doctor.
2. Avoid contact with eyes, mouth or mucous membranes.
3. If there is no improvement or aggravation of the conditions, the doctor should be consulted.

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

4.6 Pregnancy and lactation

None stated.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

None stated.

4.9 Overdose

Immediate medical advice should be sought in the event of overdosage.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

None stated.

5.2 Pharmacokinetic properties

None stated.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Acetone
Industrial Methylated Spirits 99%
Pyroxylin (Nitro Cellulose DHM 10/25)
Castor Oil
Sunset Yellow (E110)
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

The shelf life is five years from the date of manufacture.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Clear glass bottle of white flint glass type 3 containing 6.5 ml of liquid corn remover.

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

Whitehall Laboratories
Huntercombe Lane South
Taplow
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8 MARKETING AUTHORISATION NUMBER

PA 172/14/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1983

Date of last renewal: 01 April 2003

10 DATE OF REVISION OF THE TEXT

April 2003