

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Verrugon Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Salicylic acid BP 50.00% w/w.

Excipients: contains Wool fats 5.00% w/w.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Ointment.

Off-white greasy ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the treatment of verrucae (Plantar Warts).

4.2 Posology and method of administration

For Adults, Elderly and Children from 6 years onwards

1. Fix the self adhesive ring with the hole over the verruca.
2. Squeeze a little Verrugon ointment into the hole and directly on to the verruca.
3. Cover ring completely with plaster. Seal into position.
4. Wash hands after use.
5. Repeat treatment daily after gently pumicing or filing off the dead part of the verruca.

To prevent transferring infection the emery board should only be used by the patient and only for the verruca. Do not use to file nails.

Visible improvement should occur in 1 to 2 weeks but it can take up to 12 weeks for complete removal.

4.3 Contraindications

Not to be used by patients with diabetes or those with severe circulatory disorders or peripheral neuropathy except following a doctor's permission or recommendation.

Do not use if the verruca is already infected or surrounding skin is broken or inflamed.

Hypersensitivity to topical salicylate or any of the ingredients in Verrugon Ointment.

Do not use on moles, birthmarks, hairy warts or any other skin lesions for which Verrugon is not indicated.

4.4 Special warnings and precautions for use

Avoid contact with eyes or mucous membranes. If contact occurs flush with water for 15 minutes. Avoid contact with normal skin around the Verruca. Avoid using on areas of broken or damaged skin. Discontinue treatment if excessive irritation occurs.

Remove immediately any surplus ointment from normal skin tissue. Excessive prolonged use of topical salicylic acid may result in symptoms of salicylism and therefore topical salicylic acid should not be used for prolonged periods, in high concentrations, on large areas of the body.

Wool fat in this ointment may cause local skin reactions (e.g. contact dermatitis).

4.5 Interaction with other medicinal products and other forms of interaction

There are no known interactions when used as indicated. However, salicylic acid may increase the absorption of other topically applied medicines. Concomitant use of Verrugon and other topical medicines should therefore be avoided.

4.6 Fertility, pregnancy and lactation

Whilst there are no known contra-indications to the use of Verrugon during pregnancy and lactation, the safety has not been established. Verrugon should therefore be used with caution or following professional advice.

4.7 Effects on ability to drive and use machines

Not applicable, none reported.

4.8 Undesirable effects

A localised irritant reaction may occur if Verrugon is applied to normal skin surrounding the Verruca. This may be controlled by temporarily discontinuing the use of Verrugon and by being careful to apply it only to the Verruca when treatment is resumed.

4.9 Overdose

Symptoms of acute systemic salicylate poisoning have been reported after the application of salicylic acid to large areas of skin and for prolonged periods. Symptoms include dizziness, tinnitus, deafness, sweating, nausea and vomiting, headache and confusion. In children drowsiness and metabolic acidosis commonly occur, hypoglycaemia may be severe.

Salicylism may also occur in the unlikely event of large quantities being ingested. Salicylism is unlikely to occur if Verrugon is used as indicated.

Accidental oral ingestion should be treated immediately as recommended by the National Poisons Information Service.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Salicylic Acid is a bacteriostatic and fungicide. Used externally it has keratolytic properties and produces slow and painless destruction of verrucae, warts, corns and hard skin.

5.2 Pharmacokinetic properties

Salicylic acid may be percutaneously absorbed. However, there is no evidence of any systemic absorption from the use of Verrugon.

5.3 Preclinical safety data

No other information relevant to the prescriber other than that already stated in other sections of the SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

White soft paraffin
Glycerol
Light liquid paraffin
Wool fats (Lanesta S)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

5 years.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

6g collapsible aluminium tube with emery board, 9 adhesive plasters and 9 corn rings.

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

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8 MARKETING AUTHORISATION NUMBER

PA1904/002/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23 April 1992

Date of last renewal: 23 April 2007

10 DATE OF REVISION OF THE TEXT

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