Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Wartex Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Salicylic acid BP 50.00% w/w.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Ointment.
An off-white greasy ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the treatment of hard and ragged warts.

4.2 Posology and method of administration

For Adults, Elderly and Children from 6 years onwards

Topical: Apply a trace of ointment on to wart only for several days. Rub surface gently with file or pumice stone once weekly. Repeat as necessary.

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

4.3 Contraindications

Hypersensitivity to topical salicylate or any of the ingredients in Wartex ointment.

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 wart or surrounding skin is broken or inflamed.

Do not use on moles, birthmarks, unusual warts with hair growth, on facial warts in the anal or perianal area or any other skin lesions for which Wartex is not indicated.

4.4 Special warnings and precautions for use

Do not apply Wartex to soft warts or moist or tender parts of the body, avoid contact with eyes and mucous membranes. If contact occurs flush with water for 15 minutes. Avoid contact with normal skin around the Wart. 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

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 Wartex and other topical medicines should therefore be avoided.

4.6 Fertility, pregnancy and lactation

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

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

A localised irritant reaction may occur if Wartex is applied to normal skin surrounding the Wart. This may be controlled by temporarily discontinuing the use of Wartex and by being careful to apply it only to the Wart 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 Wartex is used as indicated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Salicylic acid is a bacteriostatic and fungicide Used externally it has keratolytic properties and produces gradual 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 Wartex.

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
Liquid paraffin

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

60 months

6.4 Special precautions for storage

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

6.5 Nature and contents of container

6g printed collapsible aluminium tube with membrane nozzle and HDPE screw cap.

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

PA1904/003/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 23 April 2007

10 DATE OF REVISION OF THE TEXT

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