

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Occlusal (Low Strength) 17% w/w Cutaneous Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Salicylic Acid 17% w/w

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Cutaneous solution.

Colourless to pale yellow solution with a characteristic smell of nail varnish.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Occlusal is indicated for the treatment and removal of common and plantar warts (verrucae).

4.2 Posology and method of administration

For topical application.

Prior to application soak wart in warm water for five minutes. Remove loose tissue with a brush, emery board, pumice or abrasive sponge, being careful to avoid causing pin-point bleeding or abrading the surrounding healthy skin. Dry thoroughly with a towel not used by others to avoid contagion. Carefully apply Occlusal twice to the wart using the brush applicator allowing the first application to dry before applying the second. Thereafter repeat treatment once daily or as directed by physician. Do not apply to surrounding healthy skin. Clinically visible improvement should occur in one to two weeks but maximum effect may be expected after four to six weeks.

There are no differences in dosage for children, adults or the elderly

4.3 Contraindications

Occlusal should not be used by diabetics or patients with impaired blood circulation. Do not use on moles, birthmarks, unusual warts with hair growth, on facial warts, or in the anal or perineal region.

4.4 Special warnings and special precautions for use

Occlusal is for external use only. Do not permit contact with eyes or mucous membranes. If contact occurs flush with water for 15 minutes. Do not allow contact with normal skin around wart. Avoid using on areas of broken or damaged skin. Discontinue treatment if excessive irritation occurs.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

The chronic use of this product during pregnancy and lactation, particularly when large areas of skin are involved, should be avoided.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

A localised irritant reaction may occur if Occlusal is applied to normal skin surrounding the wart. This may normally be controlled by temporarily discontinuing the use of Occlusal and by being careful to apply the solution only to the wart itself when treatment is resumed.

4.9 Overdose

Salicylism can occur following large doses of salicylic acid or prolonged use of topical salicylic preparations, or in the unlikely event of accidental consumption.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Salicylic acid has bacteriostatic and fungicidal actions, but it is its keratolytic properties which are important for this medicinal product. When applied externally it produces slow and painless destruction of the epithelium. Salicylic acid is usually applied in the form of a paint in a collodion base (10 to 17%) or as a plaster (20 to 50%) to destroy warts or corns.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

None presented.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polyvinyl butyral
Dibutyl phthalate
Isopropyl alcohol
Butyl acetate
Acrylates copolymer

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

2 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

The product is available in a flint glass cylinder (½ oz) with a white polypropylene cap that is fitted with a brush applicator.

Pack size: 15 ml.

6.6 Instructions for use and handling

Occlusal is flammable and should be kept away from flame or fire. Keep the bottle tightly capped when not in use. Do not allow the solution to drip from the brush onto the bottle neck thread, otherwise subsequent opening of the bottle may be difficult.

7 MARKETING AUTHORISATION HOLDER

Alliance Pharmaceuticals Limited
Avonbridge House
Bath Road
Chippenham
Wiltshire SN15 2BB
England.

8 MARKETING AUTHORISATION NUMBER

PA 943/7/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 31 May 1994

Date of last renewal: 31 May 2004

10 DATE OF REVISION OF THE TEXT

April 2005