Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Occlusal 26% w/w Cutaneous Solution.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Contains Salicylic Acid 26 % w/w

For a full list of excipients, see section 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

Hypersensitivity to salicylic acid or to any of the excipients.

Occlusal should not be used by diabetics or patients with impaired blood circulation. Do not use if the wart or surrounding skin is inflamed or broken. 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 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. Excessive prolonged use of topical salicylic acid may result in symptoms of salicylism and must therefore be avoided.

4.5 Interaction with other medicinal products and other forms of interactions

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

4.6 Fertility, pregnancy and lactation

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

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Undesirable effects are listed by MedDRA System Organ Classes.

Assessment of undesirable effects is based on the following frequency groupings:
Very common: ≥1/10
Common: ≥1/100 to <1/10
Uncommon: ≥1/1,000 to <1/100
Rare: ≥1/10,000 to <1/1,000
Very rare: <1/10,000
Not known: cannot be estimated from the available data

System Organ Class	Undesirable Effect	Frequency
Skin and subcutaneous tissue disorders	skin irritation*	Not known
Injury, poisoning and procedural complications	salicylism (including tinnitus)	Not known

* 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.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Symptoms of systemic salicylate poisoning have been reported after the application of salicylic acid to large areas of skin and for prolonged periods. Salicylism may also occur in the unlikely event of large quantities being ingested. Salicylism is unlikely to occur if Occlusal is used as indicated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Wart and anticorn preparations
ATC code: D11FA
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 collodian base (10 to 17%) or as a plaster (20 to 50%) to destroy warts or corns.

5.2 Pharmacokinetic properties

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

5.3 Preclinical safety data

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

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 presented in a 10 ml amber glass bottle with cap brush assembly. The cap brush assembly comprises of a black cap and a white polythene wand nylon brush with stainless steel staple.

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

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 Pharma (Ireland) Limited
United Drug Distributors, United Drug House
Magna Business Park, Magna Drive
Citywest
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA2325/011/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 31 May 1994
Date of last renewal: 31 May 2009

10 DATE OF REVISION OF THE TEXT

March 2019
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