SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Thwart 26%w/w cutaneous solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Salicylic Acid BP 26% w/w.

3. PHARMACEUTICAL FORM

Cutaneous solution.

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

Thwart 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 Thwart 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.

Thwart 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.

4.3 Contraindications

Hypersensitivity to salicylic acid or to any of the excipients.

Thwart 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

Thwart 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 interaction

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 Thwart and other topical medicines on the treated wart should therefore be avoided.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no or limited amount of data from the use of Thwart during pregnancy.

Thwart should not be used during pregnancy, except for short-term treatment of a small single wart.

It is not known if the systemic Thwart exposure reached after topical administration can be harmful to an embryo/fetus.

During the third trimester of pregnancy, systemic use of prostaglandin synthetase inhibitors may induce cardiopulmonary and renal toxicity in the fetus. At the end of the pregnancy prolonged bleeding time in both mother and child may occur, and labour can be delayed.

Breast-feeding

Whilst there are no known contra-indications to use of Thwart during lactation, the safety has not been established. Thwart 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 Thwart is applied to normal skin surrounding the wart. This may normally be controlled by temporarily discontinuing the use of Thwart 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 Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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 Thwart is used as indicated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Warts and anticorn preparations

ATC code: D11AF

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 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 Thwart.

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

Tevco vehicle 40480A, comprised of

Polyvinyl butyral B76
Dibutyl phthalate
Isopropyl alcohol
Butyl acetate
Acrylates copolymer B66

6.2. Incompatibilities

None known.

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 10ml 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. Instruction for Use/Handling

None

7. MARKETING AUTHORISATION HOLDER

Alliance Pharmaceuticals Ltd
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Wiltshire
SN15 2BB
United Kingdom

8. MARKETING AUTHORISATION NUMBER

PL 16853/0074

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

19 August 2004

10 DATE OF REVISION OF THE TEXT

12/11/2024