

PRODUCT SUMMARY

1. NAME OF THE MEDICINAL PRODUCT

Carnation callous caps
Boots medicated callous treatment plasters 40%
Tesco Medicated Callous Treatment

2.

QUALITATIVE AND QUANTITATIVE COMPOSITION

Salicylic Acid 40% w/w

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Dressings with centre ring containing Salicylic Acid Paste.

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

For the removal of callouses.

4.2. Posology and Method of Administration

One medicated dressing to be applied every three days.
Estimated treatment period six days.
Do not use for more than two weeks except after medical advice.

Dosage Adults and Elderly:

Treatment comprises 2 Medicated Dressings for topical application. A medicated dressing is placed over the callous and left in place for 3 days and then removed. The area is cleaned to remove any loose skin. The second medicated dressing may then be applied if the callous has not been completely removed.

Children:-

Children under 16 should seek medical advice before use.

4.3. Contra-Indications

Not to be used by diabetics. Patients with severe circulatory disorders should seek Professional Medical advice before use.

Do not use if callous or surrounding skin is inflamed or broken.

Do not use on patients hypersensitive to Salicylic Acid or to any of the components of the preparation.

4.4. Special Warnings and Special Precautions for Use

1) Discontinue use and remove dressing if excess discomfort or irritation is experienced, - or if sensitivity develops.

2). Do not apply to normal skin

3). Do not treat callous with any other medicated product, while using this product.

4).If symptoms persist seek professional medical advice.

5). Contains Arachis oil (peanut oil) and should not be applied by patients known to be allergic to Peanut. As there is a possible relationship between allergy to peanut and allergy to Soya, patients with Soya allergy should also avoid using this product.

4.5. Interactions with other Medicinal Products and other Forms of Interaction

None with other medicaments. Absorbed Salicylic Acid may theoretically interfere with assays for theophylline at low concentrations.

4.6 Fertility, pregnancy and lactation

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

Do not use this product during pregnancy, except for short-term treatment of a small single callous.

It is not known if the systemic exposure of this product 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.

4.7. Effects on Ability to Drive and Use Machines

Not applicable.

4.8 Undesirable effects

May cause local irritation or dermatitis.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9. Overdose

Not applicable

5. Pharmacological Properties

5.1. Pharmacodynamic Properties

Salicylic Acid has Keratolytic properties and externally applied it produces a slow destruction of the epithelium. The epidermis desquamates making the underlying layer more accessible to debridement.

5.2. Pharmacokinetic Properties

Formulation designed to provide gradual release of Salicylic Acid to restricted area of callous. It is absorbed into the outer epidermis.

5.3. Pre-clinical Safety Data

Not applicable

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Yellow Beeswax
Staybelite Resin (partially hydrogenated wood resin)
Arachis Oil
Softisan 378 (Vegetable triglyceride)
E124 Ponceau 4R
E110 Sunset Yellow

6.2. Incompatibilities

None known

6.3. Shelf Life

36 months

6.4. Special Precautions for Storage

Store at less than 30°C, away from direct sources of heat and humidity.

6.5. Nature and Content of Container

2 Medicated Dressings in a cardboard wallet or flow wrap bag, 15 wallets to one cardboard outer.

6.6 Special precautions for disposal

No special instructions apply.

7. MARKETING AUTHORISATION HOLDER

Cuxson Gerrard & Company Limited
125 Broadwell Road
Oldbury
West Midlands
B69 4BF
United Kingdom

8. MARKETING AUTHORISATION NUMBER(S)

PL 00089/5006R

**9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE
AUTHORISATION**

Date of first authorisation: 06 February 1990

Date of latest renewal: 17 January 2008

10 DATE OF REVISION OF THE TEXT

07/01/2025