Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Carnation Callous Caps 40% w/w Medicated plasters

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Salicylic Acid 40% w/w.

Also contains Arachis oil (refined), 11.6% w/w per plaster

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Medicated plaster
Dressing with a centre ring containing a 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 is six days.

Do not use for more than two weeks except after medical advice.

Dosage

Adult 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 the loose skin. The second medicated dressing may then be applied if the callous has not been completely removed.

Children:
Children under 16 years should seek medical advice before use.

4.3 Contraindications

a) Not to be used by diabetics or patients with severe circulatory disorders, except following a doctor's permission or recommendation.

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

c) Do not use if hypersensitive to Salicylic Acid, any of the components of the preparation or other NSAIDs due to the risk of cross reactivity.

d) 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.

4.4 Special warnings and precautions for use

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

b) Do not apply to normal skin or use for any other purpose.

c) Do not treat corn with any other product, while using Carnation Corn Caps.

d) If symptoms persist seek professional medical advice.

e) For external use only.

f) Do not use after the expiry date shown.

g) Keep out of reach and sight of children.

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 this product and other topical medicines on the same callous
Should therefore be avoided.

4.6 Fertility, pregnancy and lactation

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

4.7 Effects on ability to drive and use machines

No or negligible influence.

4.8 Undesirable effects

May cause local irritation or dermatitis.

4.9 Overdose

Do not treat more than 2 callouses at a time. Whilst absorption is low via this route, it is beneficial to limit the treatment to 2 callouses at a time in case undesirable sensitisation occurs.
Salicylism can occur following excessive topical application of salicylates. Symptoms include dizziness, tinnitus, deafness, sweating, nausea and vomiting, headache, and confusion.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Salicylic Acid

ATC Code D11 AF Other dermatological products.

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 Preclinical safety data

No further information available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Yellow Beeswax
Partially hydrogenated wood rosin (staybelite resin)
Arachis Oil (refined)
Vegetable triglyceride (softisan 378)
Ponceau 4R (E124)
Sunset Yellow (E110)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store below 25^{o}C. Store in the original package.

6.5 Nature and contents of container

2 medicated plasters in a cardboard wallet.

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

Cuxson Gerrard Healthcare Limited
Unit 3d North Point House
North Point Business Park
New Mallow Road
Cork

Ireland

8 MARKETING AUTHORISATION NUMBER

PA23188/001/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1983

Date of last renewal: 01 April 2008

10 DATE OF REVISION OF THE TEXT

May 2021