

## **PROFESSIONAL INFORMATION**

### **SCHEDULING STATUS**

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#### **1. NAME OF MEDICINE**

**CARNATION CORN CAPS** (36 mg (40 % w/w) PLASTER)

#### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Salicylic acid 36 mg (40 % w/w) per plaster

For full list of excipients, see section 6.1.

#### **3. PHARMACEUTICAL FORM**

Plaster

Adhesive plaster with pink ointment in the centre of a felt disc.

#### **4. CLINICAL PARTICULARS**

##### **4.1 Therapeutic indications**

Indicated for the symptomatic treatment of corns, warts and callouses.

##### **4.2 Posology and method of administration**

After a hot foot bath:

- a) Dry carefully.
- b) Apply the CARNATION CORN CAPS plaster to cover only the callosity with the pink medicated area.

c) Change the plaster every second day until the hard skin comes off itself after a hot foot bath.

Administration must be limited to approximately 10 days.

#### **4.3 Contraindications**

- Hypersensitivity to salicylic acid or any of the other ingredients in CARNATION CORN CAPS (see section 6.1).
- Not to be used by diabetics.

#### **4.4 Special warnings and precautions for use**

Children under 15 years old and people with circulatory diseases should seek professional medical advice before use.

**CARNATION CORN CAPS contain Peanut Oil. If you are allergic to Peanuts or Soya, do not use this product.**

Do not apply to broken or inflamed skin.

Ensure that the medicated portion comes into contact with the affected skin only.

Continuous use of CARNATION CORN CAPS may cause contact dermatitis.

If salicylic acid is applied to large areas of the skin, acute systemic salicylic acid poisoning can occur (See Section 4.9).

#### **4.5 Interaction with other medicines 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**

The safety of this medicine in pregnant and lactating women has not been established.

#### 4.7 Effects on ability to drive and use machines

The medicine has no or negligible influence on the ability to drive and use machines.

#### 4.8 Undesirable effects

<b>MedDRA system organ class</b>	<b>Frequency</b>	<b>Adverse reactions</b>
<b>Blood and lymphatic system disorders</b>	Frequency Unknown	Metabolic acidosis
<b>Metabolism and nutrition disorders</b>	Frequency Unknown	Ketosis
<b>Psychiatric disorders</b>	Frequency Unknown	Mental confusion, restlessness
<b>Nervous system disorders</b>	Frequency Unknown	Dizziness, headache
<b>Ear and labyrinth disorders</b>	Frequency Unknown	Tinnitus, deafness
<b>Respiratory, thoracic and mediastinal disorders</b>	Frequency Unknown	Hyperventilation, respiratory alkalosis
<b>Gastrointestinal disorders</b>	Frequency Unknown	Nausea, vomiting

<b>Skin and subcutaneous tissue disorders</b>	Frequency Unknown	Dermatitis
<b>General disorders and administration site conditions</b>	Frequency Unknown	Sweating, fever

### ***Reporting of suspected adverse reactions***

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the “6.04 Adverse Drug Reactions Reporting Form”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>

### **4.9 Overdose**

Symptoms of salicylic acid poisoning include: dizziness, tinnitus, deafness, sweating, nausea and vomiting, headache, mental confusion, hyperventilation, fever, restlessness, ketosis, respiratory alkalosis and metabolic acidosis. Treatment is symptomatic and supportive.

## **5. PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Category and class: A 13.8 Dermatological preparations: Keratolytics

ATC code : D11AF – Dermatologicals: Wart and Anti-Corn Preparations

**Applicant/PHCR:** Trinity Pharma (Pty) Ltd  
**Product Proprietary name:** CARNATION CORN CAPS

Plaster, 36 mg  
(Salicylic Acid)

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**

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

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Arachis (Peanut oil)

Pale yellow beeswax

Red paste

Staybelite Resin (Partially hydrogenated wood resin)

Softisan (Vegetable triglyceride)

### **Red paste composition**

Panceau 4R

Sunset Yellow

### **6.2 Incompatibilities**

None known

### **6.3 Shelf life**

36 Months

### **6.4 Special precautions for storage**

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Plaster, 36 mg  
(Salicylic Acid)

Store in a dry place at or below 25 °C, protect from light.

#### **6.5 Nature and contents of container**

A nylon weftstretch fabric plaster coated with a white zinc oxide adhesive with a red felt ring containing a pink salicylic acid corn paste covered by a clear embossed polyethylene release film. A strip of five adhesive plasters, in a cardboard wallet.

#### **6.6 Special precautions for disposal**

No special requirements.

### **7. HOLDER OF CERTIFICATE OF REGISTRATION**

Trinity Pharma (Pty) Ltd

106 16<sup>th</sup> Road

Midrand

1686

SOUTH AFRICA

### **8. REGISTRATION NUMBER(S)**

X/13.8/255

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

06 November 1990

### **10. DATE OF REVISION OF THE TEXT**

22 February 2024