# **Summary of Product Characteristics**

#### **1 NAME OF THE MEDICINAL PRODUCT**

Carnation Vericap Verruca Treatment 10% w/w medicated plaster

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

Each medicated plaster contains 6.5mg of salicylic acid.

For a full list of excipients, see section 6.1.

#### **3 PHARMACEUTICAL FORM**

Medicated Plaster

Carnation Vericap Verruca Treatment consists of a set of 4 sealed foil sachets each containing a medicated plaster and one sealed foil sachet containing a non-medicated protective plaster.

#### **4 CLINICAL PARTICULARS**

#### 4.1 Therapeutic Indications

A keratolytic for treatment of verrucas.

#### 4.2 Posology and method of administration

Carnation Vericap Verruca Treatment plasters are applied topically to the infected site.

#### Recommended dosage schedules:

#### **Adults**

A medicated dressing is applied to the verruca with the paste well over the verruca. Retain in place for 2 days and remove. Any loose skin is gently scraped away, the area cleaned and thoroughly dried and a fresh medicated dressing applied. Repeat this procedure over an eight day period. Apply protective plaster dressing to area to prevent infection and allow healing. If verruca is still present after four weeks, repeat treatment. Treatment is suitable for children over 6 years and adults.

Always consult the doctor before using this treatment in adults over 50 years.

#### Children

Always consult the doctor before using this treatment in children under 6 years.

### 4.3 Contraindications

Not to be used by diabetics. People with severe circulation problems should seek medical advice before use.

Do not use if skin close to the verruca is inflamed or broken.

Do not use if hypersensitive/allergic to salicylic acid, any of the components of the preparation or other NSAIDs due to the risk of cross reactivity.

#### 4.4 Special warnings and precautions for use

Dressing should be removed if excess discomfort is experienced, or if the patient is sensitised to dressing, adhesive or central medication.

The product must not be used on moles, birthmarks, hairy or genital warts. It must not be used on the face or anogenital skin.

07 May 2021 CRN00C6LH Page 1 of 4

#### **Health Products Regulatory Authority**

Verrucas are uncommon in patients over 50 years. The incidence of Ishchaemia in this group is much higher, which can result in lesions and growths being mistaken for plantar warts.

Patients over 50 years should consult a doctor before use.

Not to be used if patient has incipient gangrene.

#### 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 verruca should therefore be avoided.

#### 4.6 Fertility, pregnancy and lactation

Whilst there are no known contra-indications to theuse of this product during pregnancy and lactation, the safety has not beenestablished. Use should therefore be with caution or following professionalmedical advice.

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

Carnation Vericap Verruca Treatment has no influence on the ability to drive or use machines

#### 4.8 Undesirable effects

Mild discomfort or soreness may be experienced especially when used on weight bearing surfaces, e.g. heel or ball of foot.

#### 4.9 Overdose

Do not treat more than 3 warts at a time. Whilst absorption is low via this route, it is beneficial to limit the treatment to 3 warts 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

Keratolytic D01 AE 12

Salicylic acid has keratolytic properties and is applied topically in the treatment of hyperkeratotic and scaling skin conditions such as dandruff, ichthyosis and psoriasis. Salicylic acid is also used in the forms of a paint or as a plaster to destroy warts. Applied externally it attacks the intercellular matter between keratin molecules causing the cornified epithelium to swell, soften and shed.

The epidermis desquamates making the underlying layer more accessible to debridement.

#### 5.2 Pharmacokinetic properties

Formulation is designed to provide gradual release of salicylic acid to restricted area of the verruca. It is absorbed into the outer epidermis.

#### 5.3 Preclinical safety data

No preclinical studies were initiated by the company because the product contains an established therapeutic substance, salicylic acid, the use of which is well described in standard texts (Martindale, The Extra Pharmacopoeia; British National Formulary).

07 May 2021 CRN00C6LH Page 2 of 4

#### **Health Products Regulatory Authority**

It is well known as a treatment for warts when applied topically (Martindale, The Extra Pharmacopoeia; Neale, Common Foot Disorders; FDA Federal register 1982 vol. 47 No. 2).

#### **6 PHARMACEUTICAL PARTICULARS**

#### 6.1 List of excipients

Microcrystalline wax Hydrogenated vegetable oil

The plaster components are: felt, acrylic adhesive and PVC tape.

#### 6.2 Incompatibilities

Not applicable.

#### 6.3 Shelf life

3 years.

#### 6.4 Special precautions for storage

Store in original package away from direct sources of heat or humidity. Do not store above 25°C.

#### 6.5 Nature and contents of container

Carnation Vericap Verruca Treatment consists of 4 medicated and 1 non-medicated dressing in individual heat sealed sachets, enclosed in a printed cardboard box.

# 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**

PA23188/001/003

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

Date of first authorisation: 08 January 1990

Date of last renewal: 08 January 2010

07 May 2021 CRN00C6LH Page 3 of 4

# Health Products Regulatory Authority

# 10 DATE OF REVISION OF THE TEXT

May 2021

07 May 2021 CRN00C6LH Page 4 of 4