# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Salicylic Acid Collodion B.P. Methylated

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Salicylic Acid 12.0% w/v

For excipients, see 6.1.

## 3 PHARMACEUTICAL FORM

Topical solution.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

For the topical treatment of warts, corns or calluses.

### 4.2 Posology and method of administration

For topical application

Adults including the elderly

Apply daily to the affected areas only and allow to dry.

Children under 12 years

Children over 2 years are to be treated under medical supervision, but treatment of infants is not recommended.

Route of administration

For application to the affected areas on the surface of the skin.

## 4.3 Contraindications

Hypersensitivity to salicylic acid or to any of the excipients listed in section 6.1.

Contraindicated in diabetics or individuals with impaired peripheral blood circulation.

Contraindicated for use on facial or anogenital warts or on large areas.

Not to be used on moles, birth marks, hairy warts or any other skin lesion for which it is not indicated.

Not to be used on skin that is inflamed or broken.

## 4.4 Special warnings and precautions for use

For external use only.

Keep away from the eyes, mucous membranes and from cuts and grazes.

Avoid inhaling vapour.

Avoid spreading onto surrounding uninvolved healthy skin. If the treated area becomes inflamed or painful, treatment should be suspended until the inflammation resolves.

Highly flammable. Keep away from naked flames.

Do not use excessively.

## 4.5 Interaction with other medicinal products and other forms of interaction

No significant interactions have been reported.

## 4.6 Fertility, pregnancy and lactation

Topical application of large quantities of salicylic acid is not recommended during pregnancy or lactation.

## 4.7 Effects on ability to drive and use machines

No significant effects have been reported.

## 4.8 Undesirable effects

Salicylic acid may cause local skin irritation or inflammation and contact allergic dermatitis has been reported.

**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

**Symptoms**

Symptoms from topical administration of large quantities of salicylic acid include thirst, tinnitus, headache, lethargy, confusion, vomiting, depression and disorientation.

Symptoms of accidental oral ingestion of salicylic acid include headache, nausea, vomiting, diarrhoea and respiratory depression. Severe intoxication may result in irritability, restlessness, incoherent speech, excitement, hallucinations, delusions, delirium, mania, metabolic acidosis, stupor and coma.

**Emergency procedures**

Aspiration and gastric lavage with supportive therapy such as replacement of fluids and electrolytes.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Salicylic acid is keratolytic producing desquamation by solubilising the intercellular cement in the stratum corneum.

### 5.2 Pharmacokinetic properties

Salicylic acid is absorbed percutaneously with maximal plasma levels after 6 - 12 hours; 65-85% of the dose is absorbed.

Following percutaneous absorption, salicylic acid is distributed in the extracellular space and 58% is protein bound to albumin. Salicylates cross the placenta and appear in breast milk.

Salicylates are metabolised in the liver by microsomal enzymes and either conjugated with UDP-glucuronic acid to form phenyl or acyl glucuronides or hydroxylated into gentisic acid. In the liver and kidneys, the carboxyl groups are conjugated in the mitochondria to form salicylates or gentisurates.

65- 85% of topically administered salicylates are recoverable in the urine, 52% of which are in the form of salicyluric acid, 42% as phenolic glucuronides of salicylic acid and the rest as salicylic acid. Of a single dose, 95% is excreted within 24 hours of its entry into the extracellular space.

### 5.3 Preclinical safety data

No relevant data.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Pyroxylin
Colophony
Castor oil
Industrial methylated spirit
Solvent ether

### 6.2 Incompatibilities

Salicylic acid is incompatible with iron salts and with oxidising substances.

### 6.3 Shelf life

36 months.

### 6.4 Special precautions for storage

Store in well closed containers in a cool place remote from fire.

### 6.5 Nature and contents of container

Dispensing packs
500 ml amber glass bottle with white plastic screw cap with an aluminium faced EPE liner.
100 ml amber glass bottle with a black low density polyethylene screw cap with a polypropylene cone-shaped liner.

Patient packs or OTC packs as appropriate
5 and 10 ml amber glass bottles with a polypropylene, unwadded cap, having a small spatula attached to the cap.

Not all pack sizes may be marketed.

### 6.6 Special precautions for disposal

None

## 7 MARKETING AUTHORISATION HOLDER

Wise Pharmaceuticals Limited
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## 8 MARKETING AUTHORISATION NUMBER(S)

PL 18374/0016

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

9th March 2005

## 10 DATE OF REVISION OF THE TEXT

03/07/2015