SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Soap Liniment BPC Methylated.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Camphor 4.0% w/v**.**

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Topical solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

As a counter-irritant in the symptomatic treatment of sprains and bruises.

4.2 Posology and method of administration

Adults, the elderly and children over 12 years

Apply two to three times daily with massage to the affected parts.

Children under 12 years of age

Not recommended to be used in children under 12 years of age unless directed by a physician. Not recommended in children under 2 years of age.

Route of administration

External application.

4.3 Contraindications

Hypersensitivity to any of the ingredients.
Not to be applied to broken skin.
Do not apply near eyes or mucous membranes.
Do not use on sensitive body parts or on irritated or inflamed skin.

4.4 Special warnings and precautions for use

For external use only. This product is flammable, keep away from naked flames. Avoid excessive or prolonged use. If symptoms persist, consult your doctor.

4.5 Interaction with other medicinal products and other forms of interaction

No significant interactions have been reported.

4.6 Fertility, pregnancy and lactation

Not to be used during pregnancy or lactation unless the physician considers it necessary.

4.7 Effects on ability to drive and use machines

No significant effects would be expected under therapeutic usage.

4.8 Undesirable effects

There have been reports of instant collapse in infants following local application of camphor to their nostrils.

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 of accidental oral ingestion of camphor liniment by children include nausea, vomiting, colic, headache, dizziness, feeling of warmth, delirium, muscle twitching, epileptiform convulsions, depression of CNS and coma. Breathing is difficult and the breath has a characteristic

odour; anuria may occur. Death from respiratory failure is rare though fatalities in children have been recorded from 1 g.

Emergency procedures

Aspiration and gastric lavage. Convulsions may be controlled by diazepam or a short-acting barbiturate.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: MO2A X Other topical products for joint and muscular pain

Applied externally, camphor is a mild analgesic and rubefacient and is used as a counter-irritant.

5.2 Pharmacokinetic properties

Camphor is readily absorbed from all administration sites. It is hydroxylated in the liver to yield hydroxycamphor metabolites which are then conjugated with glucuronic acid and excreted in the urine. Camphor crosses the placenta.

5.3 Preclinical safety data

No relevant data.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Oleic acid
Potassium hydroxide
Rosemary oil
Industrial methylated spirit
Purified water.

6.2 Incompatibilities

No significant incompatibilities have been reported.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

This preparation is flammable. Keep away from a naked flame. Store in a cool place in well-closed containers.

6.5 Nature and contents of container

Dispensing packs

2000 ml white polythene bottle with a white screw cap with an aluminium faced EPE liner.

500 ml white polythene bottle with a white wadless cap.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

None

7 MARKETING AUTHORISATION HOLDER

Wise Pharmaceuticals Limited
Hani Wells Business Park
Unit 7
Hardicker Street
Manchester
M19 2RB
United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

PL 18374/0031

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

14th April 2005

10 DATE OF REVISION OF THE TEXT

10/09/2015