SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Surgical Spirit BP.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Methyl salicylate BP 0.5% v/v.

3 PHARMACEUTICAL FORM

Topical solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Used as an antiseptic for cleaning the skin and for general sickroom purposes. Intended for topical administration to human beings and as a general disinfectant.

4.2 Posology and method of administration

For children and adults, including the elderly.

4.3 Contraindications

Hypersensitivity to the actives and any of the excipients

4.4 Special warnings and precautions for use

Do not apply to broken skin.

For external use only. Caution: flammable. Keep away from naked flames.

This medicine contains 90.25% v/v ethanol in each application. It may cause burning sensation on damaged skin.

4.5 Interaction with other medicinal products and other forms of interaction

There have been reports that topical salicylates may potentiate the anticoagulant effects of warfarin.

4.6 Fertility, pregnancy and lactation

No evidence is available as to the safety of the product when used during pregnancy and lactation. In such cases therefore use with caution.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

None stated.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

This product is recommended for external use only and as such overdose is unlikely. Overdose from methyl salicylate occurs when someone accidentally or intentionally use the product orally. This may result in the development of nausea, vomiting, agitation, difficulty in breathing, dizziness and ringing in the ears, fever, acid-base disturbance etc. Also, it can cause severe, rapid-onset salicylate poisoning because of its liquid concentrated form and lipid solubility.

The management includes supportive measures, activated charcoal, IV fluids, and sodium bicarbonate.

Industrial methylated spirit

If taken internally the immediate symptoms will be those of alcohol intoxication followed by characteristic symptoms after a latent period of up to 48 hours (usually 12-18 hours). The symptoms of methanol poisoning include severe abdominal pain,

metabolic acidosis with rapid, shallow breathing and visual disturbances which may proceed to irreversible blindness. Other symptoms include headache, nausea, vomiting, diarrhoea, weakness, vertigo, ataxia, mild tachycardia, confusion, dizziness, delirium and coma which in severe cases may terminate in death due to respiratory failure or rarely in circulatory collapse.

Management of industrial methylated spirit poisoning

Recent ingestion should be treated by gastric lavage with sodium bicarbonate solution 2-5%, together with treatment for shock and respiratory failure. Acidosis should be corrected with intravenous sodium bicarbonate or compound sodium lactate.

Delirium if it occurs may be treated with diazepam. If significant amounts of methyl alcohol have been ingested, early treatment with an antidote (ethanol or fomepizole) is recommended. In severe cases haemodialysis may be effective. Treatment should not be stopped prematurely since oxidation and excretion of methyl alcohol may continue for several days; patients should, therefore, be closely observed and monitored. Suitable supportive treatment should be carried out as required.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

This product acts as an astringent.

5.2 Pharmacokinetic properties

The product contracts the skin and thus stops seepage of fluid. The alcohol is lostmainly by evaporation, the other ingredients are absorbed by the skin and excreted in the urine.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Castor oil
Diethyl phthalate
Industrial methylated spirit

6.2 Incompatibilities

None stated.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Keep away from naked flame.

6.5 Nature and contents of container

Amber glass bottle with plastic caps: l00ml, 200ml, 250ml, 500ml, 2000ml.
Plastic container with plastic cap: 2000ml

6.6 Special precautions for disposal

For external use only.
Flammable.
Keep away from naked flames.

7. MARKETING AUTHORISATION HOLDER

Crescent Pharma Ltd

Key House, Sarum Hill,

Basingstoke, RG21 8SR, UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 20416/0584

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th March 1984 / 29th June 1999

10 DATE OF REVISION OF THE TEXT

09/07/2024