

1. Name of the medicinal product

Galways Methylated Spirit

2. Qualitative and quantitative composition

Ethanol 95%

Methanol 5%

3. Pharmaceutical form

Cutaneous Solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For skin disinfection.

4.2 Posology and method of administration

Topical application.

Apply directly to unbroken skin with cotton wool.

Recommended Dose and Dosage Schedule

The product is suitable for use by adults, children and the elderly. To be used as required.

4.3 Contraindications

Hypersensitivity to methyl salicylate or any of the excipients.

4.4 Special warnings and precautions for use

Do not apply to broken skin.

Labels state:

FOR EXTERNAL USE ONLY.

Apply on unbroken skin

Store below 30°C.

Keep all medicines out of the reach of children

Caution: this preparation is flammable, keep away from naked flames.

This medicine contains 95% 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

None.

4.6 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 known.

4.8 Undesirable effects

None known.

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.

4.9 Overdose

This product is recommended for external use only and as such overdose is unlikely. Absorption of methylated Spirit through the skin, ingestion or inhalation of the vapour may produce systemic effects.

Symptoms of overdose

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 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

Applied topically, methylated spirit acts as a skin disinfectant. It may be used for skin preparation before injection.

It is applied externally for its astringent action, but mucous membranes and excoriated skin surfaces must be protected.

5.2 Pharmacokinetic properties

The effect of methylated spirit is limited to its topical use and little or none is absorbed through the skin when applied as directed.

It may however be absorbed after ingestion, inhalation or through large areas of the skin. Oxidation by alcohol dehydrogenase with formation of formaldehyde and formic acid takes place mainly in the liver and also in the kidneys. These metabolites are thought to be largely responsible for the characteristic symptoms of alcohol poisoning. Elimination of unchanged methyl alcohol via the lungs and in the urine is a minor route of excretion.

5.3 Preclinical safety data

None.

6. Pharmaceutical particulars

6.1 List of excipients

Ethanol

Methanol

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 30°C.

Flammable: Keep away from a naked flame.

6.5 Nature and contents of container

200ml PET bottle with a ropp screw cap

6.6 Special precautions for disposal and other handling

None.

7. Applicant/Manufacturer

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