

D & M ROBINS® METHYLATED SPIRIT.

(ETHYL ALCOHOL- 95%V/V)

SUBMITTED BY: NALIS PHARMACEUTICALS LTD

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SUMMARY OF PRODUCT CHARACTERISTICS

(SmPC).

1. NAME OF THE MEDICINAL PRODUCT

D & M Robins® Methylated Spirit (Ethyl Alcohol- 95%v/v)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 200ml contains:

Ethyl Alcohol BP 95%v/v

Excipients with known effect: **N/A**

BP: British Pharmacopoeia

3. PHARMACEUTICAL FORM

External Liquid

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Name of product: D & M Robins® Methylated Spirit

Composition : Ethyl Alcohol- 95%v/v

Dosage form : External Liquid

Indications: D & M Robins® Methylated Spirit is indicated for the disinfection of external (body) surfaces. Other non-pharmaceutical use include use for the removal of stains and as fuel in small lamps.

4.2 Posology and method of administration

Adults and children:

A swab of the Methylated Spirit is used to disinfect the concerned external surface.

Method of administration

Applied externally to the (body) surface

4.3 Contraindications

Hypersensitivity to any of the components of D & M Robins® Methylated Spirit

4.4 Special warnings and precautions for use

- For external use only.
- Keep away from the eyes.
- Keep out of the sight and reach of children.
- Highly flammable.

4.5 Interaction with other medicinal products and other forms of interaction

Effect of other medicinal products on Methylated Spirit

Not applicable

4.6 Fertility, pregnancy and lactation

No known side effects when externally used.

4.7 Effects on ability to drive and use machines

Not applicable since externally used.

4.8 Undesirable effects

The undesirable effects of the Methylated Spirit include drying out of the skin, skin irritation, cracking and peeling.

4.9 Overdose

Too much usage of D & M Robins® Methylated Spirit results in drying out of the skin, skin irritation, cracking and peeling.

Treatment: People who have skin irritation as a result of too much application of methylated spirit should rinse the affected surface with copious amount of water. Application of olive oil or liquid paraffin may be needed.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Disinfectant and Astringent

ATC Code: D08AX08.

Ethyl alcohol is a clear, colourless liquid rapidly absorbed in the gastrointestinal tract and distributed throughout the body. It has bactericidal activity and is used often as a topical disinfectant. It is widely used as a solvent and preservative in pharmaceutical preparations as well as serving as the primary ingredient in alcoholic beverages.

Pharmacodynamnic effect

Alcohols produce injuries to cells by dehydration and precipitation of the cytoplasm or protoplasm. This accounts for their bactericidal and antifungal actions.

Mechanism of action

Methylated Spirit acts to tighten, harden and disinfect the outer layer of the skin. It is also used for sick-room purposes.

5.2 Pharmacokinetic properties

Absorption:

Methylated Spirit may be absorbed through intact skin after excessive topical application.

Distribution:

Not applicable

Biotransformation:

Not applicable

Elimination:

Not applicable

5.3 Preclinical safety data

Not applicable

6. Pharmaceutical particulars

6.1 List of excipients

Not applicable

6.2 Incompatibilities

None known

6.3 Shelf life

Three years from the date of manufacture.

Shelf-life after dilution/reconstitution

Not applicable.

Shelf-life after first opening

Not applicable

6.4 Special precautions for storage

Store below 25°C in a dry place.

6.5 Nature and contents of container

Transparent pet bottle

6.6 Special precautions for disposal and other handling

No special requirements.

7. Marketing authorisation holder

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8. Marketing authorisation number(s)

N/A

9. Date of first authorisation/renewal of the authorization

N/A

10. Date of revision of the text

N/A