### **SKINSERV® METHYLATED SPIRIT.**

# (ETHYLALCOHOL 95% AND WOOD NAPHTHA 5%)

### **NALIS PHARMACEUTICALS LTD**

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# SUMMARYOFPRODUCTCHARACTERISTICS (SmPC).

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# 1. NAMEOFTHEMEDICINAL PRODUCT

# Skinserv® Methylated Spirit.

(Ethylalcohol 95% and Wood Naphtha 5%)

# 2. QUALITATIVEANDQUANTITATIVECOMPOSITION

Each 100ml contains:

Ethyl Alcohol BP 95%v/v Wood Naphtha BP 5%v/v

Excipients withknown effect: N/A

BP: British Pharmacopoeia

### 3. PHARMACEUTICALFORM

**External Liquid** 

#### 4. CLINICALPARTICULARS

# 4.1Therapeuticindications

Name of product: Skinserv® Methylated Spirit

Composition: Ethyl Alcohol BP 95%v/v & Wood Naphtha BP 5%v/v

Dosage form :External Liquid

Indications: Skinserv<sup>®</sup> 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.

# 4.2Posology 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

#### 4.3Contraindications

Hypersensitivity to any of the components of Skinserv® Methylated Spirit

# 4.4Special 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 Undesirableeffects

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 Skinserv<sup>®</sup> 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.

Isopropyl alcohol is an isomer of 1-propanol. It is a colourless liquid having disinfectant properties. It is used in the manufacture of acetone and its derivatives and as a solvent. Topically, it is used as an antiseptic.

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.

Methyl alcohol appears as a colourless, fairly volatile liquid with a faintly sweet pungent odor.

#### 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 30°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