



SUMMARY OF PRODUCT CHARACTERISTICS



1.1.1 SUMMARY OF PRODUCT CHARACTERISTICcS(SmPC)

1.1 Name of the medicinalproduct

Methylated spirit

1.2 Qualitative and quanlitative composition

Esoma methylated spirit contains;

Ethanol 95%

Methanol 5%

Quantitative Declaration

S/N	DESCRIPTION	QUANTITY IN 100ml	REASON FOR ADDITION
1	Ethanol	95v/v	API (denatured alcohol),
2	Methanol (wood naptal)	5v/v	API (to methyl it)
3	Water	Q s	Sufficient quantity to desired strength.

1.2 PHARMACEUTICAL FORM

Topical liquid.

Dermatological agents

100ml colourless liquid packed in 100ml transparent pet Bottles with white caps,
200ml colourless liquid packed in 200ml transparent pet bottles corked with
white caps, 2litre colourless liquid packed in a white jar corked with red caps.

2.0 Clinical particulars

Surgical spirit is a liquid which is used to clean wounds site or surgical instruments.

2.1 Therapeutic indications

Disinfectant, sterilise medical equipment, as window cleaner, perfect for
indoor or outdoor methylated heaters etc.

2.2 Posology and method of administration

Disinfectant, cleansing of wound site
Apply to affected parts.

Pediatric population

However, no pediatrics-specific problems have been documented to date.

2.3 Contraindications

Prior to diathermy

ESOMA METHYLATED SPIRIT



3.0 Special warnings and precautions for use

Avoid broken or inflamed skin, not to be ingested.

Avoid contact with mucous membranes

Product is highly flammable -administer away from naked flame.

3.1 Interaction with other medicinal products and other forms of interaction

This medicine is not known to affect other medicines.

3.2 Pregnancy and Lactation

No effect, is an external preparation.

3.3 Effects on ability to drive and use machines

None known.its external preparation but incase of accidental ingestion it can cause drowsiness.

3.4 Undesirable effects

Dry skin, Eye irritation and hypersensitivity reactions.

3.5 Overdose

Over dose may cause severe intoxication, tremors, convulsions, drowsiness, blurred vision, coma respiratory arrest, unconsciousness.

4.0 PHARMACOLOGICALPROPERTIES

Ethanol is anxiolytic, mood enhancing, sedative in nature.

it is has antibacterial effects, antiviral properties.

4.1Pre-Clinical safety data

No other relevant preclinical data available.

5.0 PHARMACEUTICAL PARTICULARS

5.1 List of excipient

water

5.2 Incompatibilities

Not applicable.

5.3 Shelf life

36 months unopened.

5.4 Special precautions for storage

Store in a dry place at 30°C away from naked flame and keep away from children



5.5 Nature and contents of container and special equipment for use, administration or implantation

100ml: PET bottle with white caps, 200ml pet bottle with white caps and 2litre jar with red caps metallic screw cap with tamper proof.

5.6 Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

6 APPLICANT/MANUFACTURER

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6.1 Marketing Authorization Number

A4-1800

6.2 Date of first authorization or renewal of the authorization.

September 19,2011

7 Date of revision of the text

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8 Dosimetry (if applicable).

Not Applicable

9 instructions for preparation of radiopharmaceuticals (if Applicable)

Not Applicable

1.3.2 LABELLING (OUTER AND INNER LABEL): Enclosed

1.3.3 PACKAGED INSERT: Not Applicable