SUMMARY OF PRODUCT CHARACTERISTICS

HARDROMED METHYLATED SPIRIT

1. NAME OF THE MEDICINAL PRODUCT

HARDROMED METHYLATED SPIRIT

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Isopropyl alcohol	70% v/v
Methanol	5% v/v

3. PHARMACEUTICAL FORM

A clear colourless solution

4. Clinical particulars

4.1 Therapeutic indications

- Methylated spirit is indicated for preparation of the skin prior to injection,
- First aid to decrease germs in minor cuts, Scrapes and burns and other conditions.
- It may be used for cleaning and disinfecting purposes.

4.2 Posology and method of administration

Methylated spirit is typically not meant for internal use. It is primarily used for external/topical applications and as directed by the physician.

Method or Route of administration:

Topical applications (For External use only)

4.3 Contraindications

Methylated spirit is contraindicated in patients who are hypersensitive or allergic to any of the ingredients in the product.

4.4 Special Warnings and Precautions for Use

Don't apply on broken skin
Label State;
FOR EXTERNAL USE ONLY.

Store below 30ºC
Keep all medicines out of the reach of children
Caution: this preparation is flammable, keep away from naked flames.

4.5 Interaction with other medicinal products and other forms of interaction

Methylated spirit is typically not meant for internal use. There is no known interaction when applied externally.

4.6 Pregnancy and Lactation

Not Applicable

4.7 Effects on ability to drive and use machines

Not Applicable

4.8 Undesirable effects

Methylated spirit may produce a burning sensation when externally applied to an open wound.

4.9 Overdose

Methylated spirit is not meant to be ingested or inhaled due to its toxicity. Ingesting or inhaling methylated spirit can lead to serious health risks.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

- Antiseptic Properties: Methylated spirit is often used as an antiseptic due to its ability to kill or inhibit the growth of microorganisms on surfaces or skin. It acts by denaturing proteins and disrupting cell membranes of bacteria and other pathogens.

- Disinfectant: Methylated spirit is used to disinfect surfaces, medical instruments, and skin. It is effective at killing a wide range of bacteria and some viruses, making it a common choice in healthcare settings.

- Drying Effect: When applied to the skin, methylated spirit can have a drying effect due to its rapid evaporation. This can be beneficial for drying out wounds and preventing bacterial growth.

5.2 Pharmacokinetic properties

Methylated spirit is not meant for internal use due to its toxic nature hence its pharmacokinetics is not available.

5.3 Preclinical safety data

None Known

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Nil

6.2 Incompatibilities

None

6.3 Shelf life

48 Months

6.4 Special precautions for storage

Storage condition: Store below 30^0C Keep out of reach of children.

6.5 Nature and contents of container

100ml clear bottle with Rubber cap

6.6 Special precautions for disposal <and other handling>

No special requirements apart from NAFDAC guidelines

7. APPLICANT

HARDIS & DROMEDAS LIMTED, HARDIS INDUSTRIAL ESTATE, AIRPORT ROAD, EMENE, ENUGU, ENUGU