

## **1. NAME OF THE MEDICINAL PRODUCT**

**(a) Brand Name:** Hyenang® Methylated Spirit.

**(b) Generic Name:** Methylated Spirit.

## **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Ethyl Alcohol 95% v/v

Wood Naphtha 5% v/v

## **3. PHARMACEUTICAL FORM**

Hyenang® Methylated Spirit solution is presented and packaged in:

(i) 100 ml transparent bottle sealed with pilfer-proof ropp caps.

(ii) 200 ml transparent bottle sealed with PVC caps.

(iii) 2 L plastic container sealed with PVC caps.

## **4. Clinical particulars**

### **4.1 Therapeutic indications**

Hyenang® Methylated Spirit is used externally as a disinfectant and antiseptic agent.

### **4.2 Posology and method of administration**

#### Posology

Liquid (External)

#### Method of administration

Hyenang® Methylated Spirit is a formulation that is externally applied as a disinfectant and an antiseptic agent. However, mucous membrane and broken skin surfaces must and should be protected from such application.

Hyenang® Methylated Spirit is usually applied undiluted to the skin before injection.

### **4.3 Contraindications**

Hyenang® Methylated Spirit should not be applied to a broken skin.

### **4.4 Special warnings and precautions for use**

### **4.5 Interaction with other medicinal products and other forms of interaction**

<Not relevant.>

### **4.6 Pregnancy and Lactation**

<Not relevant.>

#### **4.7 Effects on ability to drive and use machines**

<Not relevant.>

#### **4.8 Undesirable effects**

Hyenang® Methylated Spirit is well tolerated when applied externally on the skin but frequent application of Hyenang® Methylated Spirit may cause skin dryness and irritation.

#### **4.9 Overdose**

<Not relevant.>

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamics properties**

Pharmacotherapeutic group: Over-The-Counter (OTC) Product

#### **5.2 code: {code}**

<Mechanism of action>

<Pharmacodynamic effects>

<Clinical efficacy and safety>

<Resistance>

<Paediatric population>

#### **5.3 Pharmacokinetic properties**

<Absorption and Bioavailability>

<Distribution>

<Metabolism>

<Elimination>

<Special Population>

#### **5.4 Preclinical safety data**

Hyenang® Methylated Spirit has no teratogenic effect as it is for external use only as a disinfectant and antiseptic agent.

### **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

[List all excipients **except solvents removed during processing.**]

### **6.2 Incompatibilities**

<Not applicable.>

### **6.3 Shelf life**

36 months

### **6.4 Special precautions for storage**

25°C ± 5°C and relative humidity of 60% RH ± 5% RH.

### **6.5 Nature and contents of container <and special equipment for use, administration or implantation>**

<Not applicable.>

### **6.6 Special precautions for disposal <and other handling>**

<No special requirements.>

## **7. <APPLICANT/MANUFACTURER>**

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