

1. NAME OF THE MEDICINAL PRODUCT

(a) Brand Name: Hyenang® Surgical Spirit.

(b) Generic Name: Isopropyl Rubbing Alcohol USP.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Isopropyl Alcohol 70% v/v

Purified Water. qs

3. PHARMACEUTICAL FORM

Hyenang® Surgical Spirit solution is presented and packaged in:

(i) 200 ml transparent bottle sealed with PCV caps.

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

4. Clinical particulars

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Posology

Liquid (External)

Method of administration

Hyenang® Surgical 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.

4.3 Contraindications

Hyenang® Surgical 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® Surgical Spirit is well tolerated when applied externally on the skin but frequent application can cause nausea, vomiting, irritation of the nose and mucous membranes, throat irritations and difficulty with breathing as coughing can occur making it difficult to breath well.

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

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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