

1. NAME OF THE MEDICINAL PRODUCT

(a) Brand Name: Hyenang® Hydrogen Peroxide Solution (6%).

(b) Generic Name: Hydrogen Peroxide Solution.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Hydrogen Peroxide 6% w/v

Purified Water qs

NOTE:

Phosphoric Acid is added as a stabilizing agent.

3. PHARMACEUTICAL FORM

Hyenang® Hydrogen Peroxide Solution (6%) is presented and packaged in 100ml amber coloured bottle sealed with pilfer-proof ROPP caps.

4. Clinical particulars

4.1 Therapeutic indications

Hyenang® Hydrogen Peroxide Solution is used as Disinfectant and deodorant for cleansing of wounds as 6% v/v solution. It is used as a mouth wash in the treatment of acute stomatitis and as a deodorant gargle in 1.5% solution.

4.2 Posology and method of administration

Posology

Liquid (External)

Method of administration

Hyenang® Hydrogen Peroxide Solution (6%) is a formulation that is for external use only. The product is safe and well tolerated when applied topically as an antiseptic and disinfectant.

The product is applied to the affected part (wound) topically with the aid of cotton wool or any suitable sterile applicator/gauze once daily or as directed by the physician.

4.3 Contraindications

Hyenang® Hydrogen Peroxide Solution (6%) is incompatible with reducing agents, including organic matter and oxidizable substance, and with some metals, metallic salts, alkali, iodides, permanganates and other stronger oxidizing agents. The product is comparatively stable in the presence of a slight excess of acid. Decomposition of the product is increased by light, agitation, and heat. Incompatibility may also produce decomposition as well as allowing it to become alkaline.

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® Hydrogen Peroxide Solution (6%) is well tolerated when applied externally. However, it is dangerous to inject or instill Hydrogen Peroxide into closed body cavities from which the released oxygen has no free exit. Colonic lavage with solution of Hydrogen Peroxide solution has been followed by gas embolism, rupture of the colon, proctitis, ulcerative colitis and gangrene of the intestine.

The continued use of Hydrogen Peroxide as a mouth wash may cause reversible hypertrophy of the papillae of the tongue.

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® Hydrogen Peroxide Solution (6%) has no teratogenic effect as the product is applied topically and is not absorbed from the site of application.

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

24 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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