1. NAME OF THE MEDICINAL PRODUCT

(a) Brand Name: Hyenang® Eusol
(b) Generic Name: Calcium Hypochlorite and Boric Acid

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlorinated lime B.P 1.25% w/v
Boric acid B.P 1.25% w/v
Purified water B.P qs

3. PHARMACEUTICAL FORM

Hyenang® Eusol solution is presented and packaged in 200ml Amber Round PET Bottles for Chlorinated Lime solution while the Boric Acid solution is packaged in 200ml Flint Round PET Bottles sealed with plastic caps.

4. Clinical particulars

4.1 Therapeutic indications

Hyenang® Eusol as a disinfectant is for external use in wound dressing and cleansing agent. It is used in all stages of wound management and in the management of different types of wounds. It is used to disinfect wounds, assist in the removal of slough and to promote the healing of pressure sores and leg ulcers.

4.2 Posology and method of administration

Posology
Liquid (External)

Method of administration
Hyenang® Eusol is a formulation that is externally applied as a disinfectant.

4.3 Contraindications

Hyenang® Eusol contains calcium hypochlorite and boric acid. Accidental swallowing can cause the followings: stomachache, a burning sensation, coughing, diarrhoea, a sore throat, and vomiting. Hypersensitivity is a contraindication.

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

Hyenang® Eusol should not be used if you have the following conditions:

- ✓ Breastfeeding
- ✓ Pregnancy

4.7 Effects on ability to drive and use machines

<Not relevant.>

4.8 Undesirable effects

Hyenang® Eusol contains calcium hypochlorite and boric acid. It is only meant for external use and users who suffer from skin disease such as eczema should avoid using it. Accidental calcium hypochlorite poisoning can be deadly. Severe injuries can occur to the mouth, throat, oesophagus, and stomach. Severe injuries include bleeding, holes in body tissues and permanent scars and narrowing of the oesophagus. Breathing chlorine gas from calcium hypochlorite solutions causes nasal irritation, sore throat, and coughing. Skin contact with low levels of this chemical irritates the skin but strong calcium hypochlorite solutions cause burning pain, redness, swelling and blisters. Eye contact with mild bleach solutions may cause short-term mild irritation but solutions that are more powerful cause severe eye injuries.

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

No data was available from studies in humans on the carcinogenicity of hypochlorite salts and there was inadequate evidence for the carcinogenicity of hypochlorite salts in experimental animals. Overall, The International Agency for Research on Cancer (IARC) classified calcium hypochlorite as a category 3 carcinogen, i.e. not classifiable as to the carcinogenicity to humans. Calcium hypochlorite is not considered to be a reproductive toxin. There are no studies on the effect of direct exposure to calcium hypochlorite bleach in pregnancy. There is limited data on the effects of exposure to calcium hypochlorite in drinking water. This data does not provide evidence of an increased risk of congenital malformations. However, there is some evidence of other outcomes including an increased risk of pre-term delivery, reduced foetal head circumference and decreased body length (UK National Teratology Information Service (UKTIS), 2012).

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^{o}C± 5^{o}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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