1. NAME OF THE MEDICINALPRODUCT

(a) Generic Name: Calcium Hypochlorite and Boric Acid

2. QUALITATIVE AND QUANTITATIVECOMPOSITION

SN	DESCRIPTION	QUANTITY/200 ML
1	Iodine.	2.50 g
2	Potassium Iodide	1.250 g

3. PHARMACEUTICAL FORM

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 Therapeuticindications

It is used as an antisceptic application for small wounds and abrasions as a 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 ofadministration

Posology

Liquid (External)

Method of administration

Eusol is a formulation that is externally applied as a disinfectant.

4.3 Contraindications

Alcoholic Iodine solution contains Iodine and and Potassium Iodide. 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 foruse

4.5 Interaction with other medicinal products and other forms ofinteraction

<Not relevant.>

4.6 Pregnancy and Lactation

This product should not be used if you have the following conditions:

- ✓ Breastfeeding
- ✓ Pregnancy

4.7 Effects on ability to drive and usemachines

<Not relevant.>

4.8 Undesirableeffects

The product contains Iodine and Potassium Iodide. It is only meant for external use and users who suffer from skin disease such as eczema should avoid using it. 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. Skin contact with low levels of this chemical irritates the skin.

4.9 Overdose

<Not relevant.>

5 PHARMACOLOGICALPROPERTIES

5.9 Pharmacodynamics properties

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

5.10 code:{code}

<Mechanism of action>

<Pharmacodynamic effects>

<Clinical efficacy and safety>

<Resistance>

<Paediatric population>

5.11 Pharmacokinetic properties

<Absorption and Bioavailability>

<Distribution>

<Metabolism>

<Elimination>

<Special Population>

5.12 Preclinical safety data

No data was available from studies in humans on the carcinogenicity of Potassium iodide salts and there was inadequate evidence for the carcinogenicity of iodine 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. 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 PHARMACEUTICALPARTICULARS

6.9 List ofexcipients

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

6.10 Incompatibilities

<Not applicable.>

6.11 Shelflife

24 months

6.12 Special precautions forstorage

25^{o}C± 5^{o}C and relative humidity of 60% RH ± 5% RH.

6.13 Nature and contents of container <and special equipment for use, administration or implantation>

<Not applicable.>

6.14 Special precautions for disposal <and otherhandling>

<No special requirements.>

7 <APPLICANT/MANUFACTURER>

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