MAGZO
PHARMACEUTICAL & LABS LTD
ADDRESS:No 25, Crestfield Avenue, Peace Estate, Gama Kwari, Jaba,
Nassarawa LGA, Kano State
PHONE NO: 08066894569 E-MAIL: magzopharmaceutical@gmail.com

SUMMARY OF PRODUCT CHARACTERISTICS
EUSOL SOLUTION

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SUMMARY OF PRODUCT CHARACTERISTICS EUSOL SOLUTION

Summary of Product Characteristics

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9. Date of first authorisation/renewal of the authorisation
10. Date of revision of the text

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1. Name of the medicinal product
EUSOL SOLUTION

2. Qualitative and quantitative composition

Active:
Chlorinated Lime B. P.
Boric Acid B. P.

For a full list of excipients, see section 6.1.

3. Pharmaceutical form
Solution
Clear colorless solution

4. Clinical particulars

4.1 Therapeutic indications
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
For Topical use. Applied directly to skin

Recommended dose and dosage schedule

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The product is suitable for use by adults, children and the elderly.
Apply gently with a pad of cotton wool to the affected parts as required.

4.3 Contraindications

Eusol contains calcium hypochlorite and boric acid. Accidental swallowing can cause the followings: stomachache, a burning sensation, coughing, diarrhea, a sore throat, and vomiting.
Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1

4.4 Special warnings and precautions for use

For external use only.
Keep all medicines away from children.

4.5 Interaction with other medicinal products and other forms of interaction

Not relevant.

4.6 Fertility, pregnancy and lactation

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

- Breastfeeding
- Pregnancy.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

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.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

4.9 Overdose
Not relevant.

5. Pharmacological properties
5.1 Pharmacodynamic properties
Sodium hypochlorite is a chemical compound with the formula NaClO. It is composed of a sodium cation and a hypochlorite anion; it may also be viewed as the sodium salt of hypochlorous acid. When dissolved in water, it is commonly known as bleach and is frequently used as disinfectant or a bleaching agent.

5.2 Pharmacokinetic properties

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An antiseptic solution prepared from chlorinated lime and boric acid, formally used in treating wounds. It is used in surgical dressing to remove the slough or necrotic tissue form the wound and it helps in effective healing. Found most effective in pseudomonads organism.

5.3 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

PURIFIED WATER
CONC. Hcl

6.2 Incompatibilities

None known

SUMMARY OF PRODUCT CHARACTERISTICS
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6.3 Shelf life
36 months

6.4 Special precautions for storage
Do not store above 30°C

6.5 Nature and contents of container

Bottle:	Amber PET
Closures:	28mm ROPP, tamper evident, child resistant.
Pack Sizes:	100ml.

6.6 Special precautions for disposal and other handling
No special requirements.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required (these should be disposed of in line with local requirements). These measures will help to protect the environment.

7. Marketing authorisation holder
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NA

10. Date of revision of the text
Not Applicable