SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal Product

1.1 Name of the medicinal Product

Chlorinated Lime BP

Boric Acid BP

1.2 Strength

Chlorinated Lime	1.25g
Boric Acid	1.25g

1.3 Pharmaceutical Form

Topical solution

Transparent solution filled in PET bottle.

2. Qualitative and Quantitative Composition

2.1 Qualitative declaration

Each 100ml of Esoma Eusol Solution contains;

Chlorinated Lime + Boric Acid

2.2 Quantitative declaration

S/N	INGREDIENT	SPECIFICATION	QUANTITY in 60ml	REASON for INCLUSION
1	Chlorinated Lime	BP	1.25g	Bleaching Agent. Disinfectant
2	Boric Acid	BP	1.25g	Antiseptic for minor burns and cuts

3. Pharmaceutical Form

Topical solution

Transparent solution filled in PET bottle.

4. Clinical Particulars

4.1 Therapeutic Indications

Indicated in the disinfection and treatment of wound, ulcers cleaning and wet dressing. Protects against infection and prevents the growth of bacteria, fungi and viruses.

Dosage

As directed by the physician.

4.2 Posology and Method of Administration

Used externally. Add EUSOL A into equal amount of EUSOL B before using as an antiseptic wound dressing. The mixture should be used within 2 weeks of its preparation.

Pediatric population

Not to be used on children within the age of 1 to 2 years.

4.3 Contraindications

None Known

4.4 Special Warnings and Special Precautions for Use

Any remaining mixed solution must be discarded after 14 days.

Avoid using it on any open wounds or other skin injury around the eyes.

Do not use it along with other medications without medical supervision.

Do not use it to treat any infection without doctors' advice.

FOR EXTERNAL USE ONLY.

4.5 Interaction with other medicinal products and other forms of interaction

Eusol Lotion may interact with the following drugs and products:

- Hypochlorite
- Iron(III) chloride
- Nickel
- Riboflavin

4.6 Fertility, Pregnancy and Lactation

Systemic absorption unknown, avoid topical use on nipple.

4.7 Effects on ability To Drive and use Machines

None.

4.8 Undesirable Effects

Application may cause stinging.

4.9 Overdose

Not ingestible.

5. Pharmacological Properties

5.1 Pharmacodynamics Properties

Sodium hypochlorite is a chemical compound with the formular 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 agengt.

5.2 Pharmacokinetic Properties

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 organisms.

5.3 Preclinical Safety Data

No other relevant preclinical data is available.

6. Pharmaceutical Particulars

6.1 List of Excipients

Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

36 months unopened.

6.4 Special Precautions for Storage

Store below 30^{o}C, protect from light.

6.5 Nature and Contents of Container

100ml: PET bottle with white 28mm plastic cap.

6.6 Special precaution for disposal and other handling

Dispose waste or unused product in accordance with local requirements.

7. Registrant (Marketing Authorization Holder And Manufacturing Site Addresses)

7.1 Name and Address of Marketing Authorization Holder

Esoma Pharmaceutical Ltd

Plot 54 cadastral zone 07-05 Extension 2, kubwa, Abuja.

Tel: 08036786233

Email: esomapharmacy@gmail.com

7.2 Name and Address of manufacturing site(s)

Esoma Pharmaceutical Ltd

Plot 54 cadastral zone 07-05 Extension 2, kubwa, Abuja.

Tel: 08036786233

Email: esomapharmacy@gmail.com

7.3 Marketing Authorization Number

To be included after obtaining first registration.

7.4 Date of First <Registration> / Renewal of The <Registration>

It will be applicable after registration of this product.

8. Date of Revision of the Text

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9. Dosimetry (If Applicable)

Not Applicable

10. Instructions for preparation of radiopharmaceuticals (if Applicable)

Not Applicable