SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Of

DE-SHALOM EUSOL SOLUTION

1. Name of the medicinal product

DE-SHALOM EUSOL SOLUTION

2. Qualitative and quantitative composition

Chlorinated Lime	1.25%w/v	(Solution A)
Boric acid	1.25%w/v	(Solution B)

For a full list of excipients, see section 6.1.

3. Pharmaceutical form

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

The product is suitable for use by adults, children and the elderly.

Mix equal volume of Solution A with Solution B and 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 Applicable

4.6 Fertility, pregnancy and lactation

Not Applicable

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 Applicable

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.

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.

5.2 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

6.2 Incompatibilities

None known

6.3 Shelf life

18 months

6.4 Special precautions for storage

Store below 30°C

6.5 Nature and contents of container

100 ml Amber bottle

6.6 Special precautions for disposal and other handling

No special requirements.

7. Marketing authorisation holder / Manufacturer

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