Professional information for SAVLON® ANTISEPTIC

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

SAVLON® ANTISEPTIC Liquid

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 mL contains:

Cetrimide	3,0 g
Chlorhexidine gluconate	0,3 g

For the full list of excipients, see section 6 .1.

3. PHARMACEUTICAL FORM

Liquid.

A clear, orange-yellow liquid with a pine-like odour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

General purpose antiseptic cleanser.

4.2 Posology and method of administration

FOR EXTERNAL USE ONLY.

Minor cuts, abrasions, stings and insect bites: Dilute 5 mL in 100 mL water.

General antiseptic cleansing: Dilute 60 – 90 mL in 1,0 – 1,5 litre of water.

4.3 Contraindications

- Hypersensitivity to cetrimide, chlorhexidine gluconate any of the other ingredients (see section 6.1).
- For external use only.
- SAVLON® ANTISEPTIC should not come into direct contact with the eyes, brain, meninges or middle ear. Do not use in body cavities.

4.4 Special warnings and precautions for use

SAVLON® ANTISEPTIC should not be applied repeatedly to the skin and wet dressings should not be left in contact, as sensitivity may occur.

Ototoxicity has been reported after direct instillation into the middle ear. Do not use around the ears, eyes, nose or mouth to avoid contact with the eardrum, eyes and mucous membranes.
If SAVLON® ANTISEPTIC is accidentally splashed into the eye, the open eye should be irrigated with water for at least 10 minutes.

If symptoms persist or worsen, or if new symptoms occur, stop use and consult a doctor. Serious allergic reactions (skin rash, itching, hives, anaphylaxis, including shock, have been rarely reported with the use of chlorhexidine gluconate, as in SAVLON® ANTISEPTIC (see section 4.8).

Do not cover the wound/s after use of external medicine.

SAVLON® ANTISEPTIC should be diluted as recommended to avoid skin burns.

Hypochlorite bleaches may cause brown stains to develop in fabrics which have previously been in contact with SAVLON® ANTISEPTIC. An oxidising bleach such as sodium perborate should be used in laundering.

SAVLON® ANTISEPTIC is incompatible with anionic agents and its activity is reduced in the presence of organic matter and soap.

SAVLON® ANTISEPTIC contains benzyl benzoate

SAVLON® ANTISEPTIC may cause non-immunologic immediate contact reactions by a possible cholinergic mechanism.

4.5 Interaction with other medicines and other forms of interaction

There are no known medicine interactions associated with SAVLON® ANTISEPTIC.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no adequate and well-controlled studies in pregnant or lactating women.

SAVLON® ANTISEPTIC should not be used during pregnancy.

Lactation

If SAVLON® ANTISEPTIC was used as an antiseptic cleanser by a mother who is breastfeeding, the mother's nipples should be rinsed thoroughly with water before commencing breastfeeding.

Ask a doctor before use if you are pregnant or breastfeeding.

4.7 Effects on ability to drive and use machines

SAVLON® ANTISEPTIC is for external use only and is not expected to have an effect on the ability to drive and use machinery.

4.8 Undesirable effects

Idiosyncratic reactions may occur.

Immune system disorders:

Less frequent: Hypersensitivity reactions, including anaphylaxis.

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of SAVLON® ANTISEPTIC is important. It allows continued monitoring of the benefit/risk balance of SAVLON® ANTISEPTIC. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

For further information, please contact the Johnson & Johnson call centre on 0860 410032 (landline).

4.9 Overdose

SAVLON® ANTISEPTIC is poorly absorbed across intact mucous membranes following local application.

Accidental ingestion could cause nausea and vomiting, dyspnoea, sore throat, abdominal pain and cyanosis due to paralysis of the respiratory muscles, possibly leading to asphyxia.

Depression of the central nervous system, with convulsions, hypertension and coma, may occur.

Empty stomach by aspiration and lavage. Treatment is symptomatic and supportive. Accidental

ingestion of SAVLON® ANTISEPTIC by infants resulted in various degrees of erythema, ulceration and necrotic lesions on the circumoral and mouth region.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A: 13.1 Antiseptics, Disinfectants and Cleansing Agents.

Pharmacotherapeutic group: Antiseptics and Disinfectants

ATC code: D08AC52 Chlorhexidine combinations

SAVLON® ANTISEPTIC has detergent and antiseptic cleansing properties.

Cetrimide

The mode of action of quaternary ammonium compound (QAC) is antiseptic against bacterial cells involves a general perturbation of lipid bilayer membranes as found to constitute the bacterial cytoplasmic membrane and the outer membrane of Gram-negative bacteria. Such action leads to a generalised and progressive leakage of cytoplasmic materials. Low concentrations of QAC bind firmly to anionic sites found on the membrane surface, causing cells both to lose osmoregulatory capability and to leak potassium ions and protons. Cetrimide is a QAC with actions typical of cationic surfactants. These surfactants dissociate in aqueous solution into a relatively large and complex cation that is responsible for the surface activity and a smaller inactive anion. In addition to emulsifying and detergent properties, QAC have bactericidal activity against Gram-positive bacteria and, at a higher concentration against some Gram-negative bacteria.

Chlorhexidine gluconate

Chlorhexidine gluconate is a bisbiguanide antiseptic and disinfectant that provides antiseptic and

antimicrobial effects with rapid bactericidal action against wide range of Gram-positive and Gram-negative bacteria. It precipitates the bacterial cytoplasm and it also interferes with membrane function by inhibiting oxygen utilization leading to a decrease in cellular ATP levels. These forms of destabilization lead to the destruction of the cell's integrity and eventually causing cell death. In Gram-negative bacteria, chlorhexidine affects the outer membrane allowing the release of periplasmic enzymes. The inner membrane of these organisms is not ruptured but the uptake of small molecules is impaired. At low concentrations, chlorhexidine exhibits a bacteriostatic effect, while at high concentrations, it is bactericidal. Chlorhexidine has bacteriostatic, bactericidal, fungicidal, fungistatic and some virucidal activity.

5.2 Pharmacokinetic properties

Cetrimide

There is no information available regarding the pharmacokinetics of formulations containing cetrimide or its metabolites in human subjects.

Chlorhexidine gluconate

When used topically, the *N*-chlorinated derivative of chlorhexidine binds covalently to proteins in the skin and mucosa with limited systemic absorption. Chlorhexidine can be absorbed through intact skin although there is no suggestion that chlorhexidine gluconate accumulate in the blood with repeated exposures.

The estimated elimination half time of the chlorhexidine is 4 days.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl benzoate (preservative)

D&C Yellow No. 10 (colourant)

d-Gluconolactone (for pH adjustment)

FD&C Yellow No. 6 (colourant)

Industrial methylated spirits

Propyl alcohol (preservative)

Purified water

Salvo AP1022 (perfume)

Sodium hydroxide (for pH adjustment) (E525)

Terpineol (perfume)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

4 years.

6.4 Special precautions for storage

Store at or below 25 ºC.

Protect from light.

KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

Clear, PVC or PET bottle with a white cap containing 50 mL, 75 mL, 125 mL, 250 mL, 500 mL, 750 mL, 1 Litre or 2 Litre. Natural HDPE containers of 5 Litres.

6.6 Special precautions for disposal and other handling

Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

7. HOLDER OF CERTIFICATE OF REGISTRATION

Johnson & Johnson (Pty) Ltd.

241 Main Road

Retreat 7945

SOUTH AFRICA

8. REFERENCE NUMBER

G1393 (Act 101/1965)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30 August 1984.

10. DATE OF REVISION OF THE TEXT

18 October 2021

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