SAVLON® ANTISEPTIC

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

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SAVLON® ANTISEPTIC Liquid

Cetrimide / Chlorhexidine gluconate

Read all of this leaflet carefully because it contains important information for you.

SAVLON® ANTISEPTIC is available without a doctor's prescription. Nevertheless, you still need to use SAVLON® ANTISEPTIC carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share SAVLON® ANTISEPTIC with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What SAVLON® ANTISEPTIC is and what it is used for.
2. What you need to know before you use SAVLON® ANTISEPTIC.
3. How to use SAVLON® ANTISEPTIC.
4. Possible side effects.
5. How to store SAVLON® ANTISEPTIC.
6. Contents of the pack and other information.

1. What SAVLON® ANTISEPTIC is and what it is used for

SAVLON® ANTISEPTIC liquid has detergent and antiseptic cleansing properties. It is used as a general purpose antiseptic cleanser.

2. What you need to know before you use SAVLON® ANTISEPTIC

Do not use SAVLON® ANTISEPTIC LIQUID:

- If you are hypersensitive (allergic) to cetrimide, chlorhexidine gluconate or any of the other ingredients of SAVLON® ANTISEPTIC.
- Near your eyes, brain, middle ear or in any body cavities.

Warnings and precautions

Take special care with SAVLON® ANTISEPTIC:

- Do not use undiluted on the skin.
- Do not apply repeatedly to the skin and wet dressings should not be left in contact, as sensitivity may occur.
- Do not use around the ears, eyes, nose or mouth to avoid contact with the eardrum, eyes, and mucous membranes. Ototoxicity has been reported after direct instillation into the middle ear. Treat any accidental splashes to the eyes by washing open eyes with water for at least ten minutes and seek medical advice.
- Inform your doctor if you experience any allergic reaction to SAVLON® ANTISEPTIC.
- Do not cover your wounds if you have used any other medicine.
- Dilute SAVLON® ANTISEPTIC as instructed to avoid skin burns.
- Brown stains may develop on fabric which comes in direct contact with SAVLON® ANTISEPTIC. An oxidising bleach such as sodium perborate should be used when doing the laundry.
- Organic matter and soap reduce the activity of SAVLON® ANTISEPTIC.

Other medicines and SAVLON® ANTISEPTIC

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

No known interactions.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using SAVLON® ANTISEPTIC.

Do not use SAVLON® ANTISEPTIC during pregnancy.

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

Driving and using machines

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

3. How to use SAVLON® ANTISEPTIC

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.

Always use SAVLON® ANTISEPTIC exactly as described in this leaflet or as instructed. Check with your doctor or pharmacist if you are not sure.

If you have the impression that the effect of SAVLON® is too strong or too weak, tell your doctor or pharmacist.

If you use more SAVLON® ANTISEPTIC than you should

In the event of overdosage or accidental ingestion consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and the rest of the remaining SAVLON® ANTISEPTIC with you so the doctor will know what you have taken.

4. Possible side effects

SAVLON® ANTISEPTIC can have side effects.

Not all side effects reported for SAVLON® ANTISEPTIC are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using SAVLON® ANTISEPTIC, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop using SAVLON® ANTISEPTIC and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- Rash or itching
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to SAVLON® ANTISEPTIC.

You may need urgent medical attention or hospitalisation.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of SAVLON® ANTISEPTIC.

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

5. How to store SAVLON® ANTISEPTIC

- Store at or below 25 °C.
- Protect from light.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the label.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SAVLON® ANTISEPTIC contains

The active substances are cetrimide and chlorhexidine gluconate.

Each 100 mL contains 3,0 g cetrimide and 0,3 g chlorhexidine gluconate.

The other ingredients are:

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).

What SAVLON® ANTISEPTIC looks like and contents of the pack

SAVLON® ANTISEPTIC is a clear, orange-yellow liquid with a pine-like odour.

SAVLON® ANTISEPTIC is packed in a 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.

Holder of certificate of registration

Johnson & Johnson,

241 Main

Road, Retreat,

7945,

South Africa.

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Access to corresponding Professional Information

The latest electronic Professional Information & Patient Information Leaflet may be found at the SAHPRA website: https://www.sahpra.org.za/pi-pil-repository/.

Alternatively, you may directly contact Johnson & Johnson (Pty) Ltd.:

Consumer Contact Centre:

0860 410032 (South Africa Only)

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