

Videne
7.5% w/w Surgical Scrub
(Iodinated povidone)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What it is and what it is used for
2. What you need to know before use
3. How to use
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6. Contents of the pack and other information

1. What it is and what it is used for

This product, referred to as Videne Surgical Scrub in this label-leaflet, contains iodinated povidone as the active substance. It is an antiseptic skin cleanser for use as a pre-operative skin disinfection for the surgical team and for disinfecting the site of incision prior to surgery.

Solutions of iodinated povidone gradually release iodine to kill or stop the growth of bacteria, fungi, viruses, protozoa, cysts and spores.

2. What you need to know before you use

Do not use:

- On newborn children.
- During pregnancy and breastfeeding.
- If you are sensitive to iodine or any of the other ingredients of this medicine (listed in section 6).
- For regular or prolonged periods if you have thyroid problems or if you are taking lithium (an anti-depressant).
- For external use only. Do not swallow.

Warnings and precautions:

Talk to your doctor or nurse before using Videne Surgical Scrub if:

- You are using on large wounds or severe burns as it could produce adverse effects such as changes in blood chemistry and problems with the kidneys.
- You are prone to, or have ever been treated in the past for hyperthyroidism.

Other medicines and Videne Surgical Scrub

- Talk to your doctor or nurse before using Videne Surgical Scrub if you are taking any other medicines, specifically:
 - Wound treatments.

- Other skin disinfectants.
- Certain antiseptics, as dark discolouration can occur at the areas treated.
- Lithium (see 'Do not use').
- False positive results may occur in certain stool or urine tests.
- The results of certain thyroid tests may be affected.

Pregnancy and breast-feeding

Do not use Videne Surgical Scrub if you are pregnant or breast-feeding.

3. How to use

PRE-OPERATIVE SURGICAL SCRUB

Wet hands and forearms, apply approximately 3.5ml of Videne Surgical Scrub and rub it in thoroughly on these areas for a minimum of two minutes. A brush may be used to scrub the fingernails. Add water to develop a lather before rinsing thoroughly under running water.

PRE-OPERATIVE SKIN PREPARATION

The site of incision should be washed with Videne Surgical Scrub two or three times prior to the operation and then immediately before surgery. Wet the area to be cleaned and apply sufficient Videne Surgical Scrub to make cleansing easy. Wash the area for two minutes with sterile gauze wetted with water. Develop a lather and rinse thoroughly.

ONLY WATER should be used to dilute Videne Surgical Scrub

There are no special recommendations for the amounts used on children or elderly patients.

Action to be taken if swallowed:

If Videne Surgical Scrub is accidentally swallowed go to the accident and emergency department of your nearest hospital.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

- Skin reactions may occur but these are very rare affecting fewer than 1 in 10,000 people.
- The absorption of iodine through intact or damaged skin may interfere with thyroid function tests.

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via: HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2. Tel: +353 1 6764971 Fax: +353 1 6762517 Website: www.hpra.ie, e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store

Keep out of the sight and reach of children. Do not store above 25°C. Do not use after the expiry date on the front label. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

Videne Surgical Scrub contains 7.5%w/w of the active substance iodinated povidone equivalent to 8.25 mg/ml iodine. The other ingredients are polyoxyl 40 hydrogenated castor oil, macrogol 400, C12-C13 pareth-9, glycerol, povidone, citric acid, anhydrous disodium hydrogen phosphate and purified water.

Videne Surgical Scrub is a dark reddish brown liquid, supplied in a 500 ml HDPE bottle sealed with a plastic screw cap.

Marketing Authorisation Holder & Manufacturer

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Text revised November 2022

The following information is intended for medical or healthcare professionals only.

Incompatibilities

Videne Surgical Scrub may interact with protein and other organic substances.

The treatment area should be irrigated to remove as much blood as possible before using Videne Surgical Scrub. It should not be used with reducing agents, alkaloid salts, tannic acid, salicylic acid, silver, mercury and bismuth salts, taurolidine and hydrogen peroxide. Absorption of iodine from povidone-iodine through either healthy or damaged skin may interfere with thyroid function tests. Videne Surgical Scrub may also interfere with tests for haemoglobin or glucose in stool or urine samples.

Treatment of overdose

The stomach should be washed out with dilute starch and protein-containing foods or a 1% solution of sodium thiosulphate. Dialysis should be carried out to reduce serum iodine levels and thyroid function should be monitored. Other possible symptoms such as metabolic acidosis or renal dysfunction should be treated as appropriate.