

Package leaflet: Information for the patient

Videne Antiseptic Solution 10% w/w Cutaneous Solution

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 if you need more information or advice.
- If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet.
- You must talk to a doctor if you do not feel better or if you feel worse after 5 days.

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
4. Possible side effects
5. How to store
6. Contents of the pack and other information

1. What it is and what it is used for

This product, referred to as Videne Antiseptic Solution in this label-leaflet, contains povidone-iodine as the active substance. It is used by a doctor or nurse to disinfect skin (e.g. prior to surgery, biopsies, injections, punctures, blood taking, bladder catheterisations) or mucous membranes such as the mouth, eye, bowel and female genitals. It can also be used by a patient for self-treatment as an antiseptic treatment for wounds, superficial and limited burns and infected skin. Videne Antiseptic Solution gradually releases iodine to help destroy bacteria, fungi and some viruses.

2. What you need to know before use

Do not use:

- If you have hyperthyroidism (an over-active thyroid gland) or other thyroid disorders.
- If you have Duhrings's disease (a skin disease with severe itching and blistering).
- Before or immediately after radioiodine therapy.
- If you know that you are sensitive to iodinated povidone or any of the ingredients.
- For regular or prolonged periods if you are taking lithium (an anti-depressant).

Warnings and precautions

Talk to your doctor, nurse or pharmacist before using Videne Antiseptic Solution.

Due to the risk of hyperthyroidism, consult your doctor before use:

- On infants under 6 months old
- On elderly patients
- If you are prone to, or have been treated in the past for hyperthyroidism or thyroid diseases.
- If you intend to use the solution for longer than 5 days or on a large area of skin.
- If you have thyroid swelling (bland multinodular goitre).

In these cases, the doctor should be vigilant for early symptoms of possible hyperthyroidism for up to 3 months after therapy has been discontinued and, where necessary, thyroid function should be monitored. In infants up to the age of 6 months, after applying Videne Antiseptic Solution thyroid

function should be checked. In the case of hypothyroidism, early treatment with thyroid hormones must be carried out until thyroid function becomes normal. Accidental oral intake by the nursing infant must be avoided. Videne Antiseptic Solution contains the excipient macrogolglycerol hydroxystearate. This may cause skin reactions.

Other medicines and Videne Antiseptic Solution

Tell your doctor if you are using, have recently taken or might use and other medicines, specifically:

- Other Wound treatments
- Other disinfectants.
- Certain antiseptics, as dark discolouration can occur at the treated areas.
- 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, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before use. Videne Antiseptic Solution should be only used with extreme caution if you are pregnant or breast-feeding.

3. How to use this product

Always use this medicine exactly as described in this leaflet or as your doctor has told you. Check with your doctor or nurse if you are unsure. Do not use for longer than 5 days, or on a large area of skin, without first consulting your doctor.

The frequency and duration of application depends on the indication for use. Videne Antiseptic, freshly prepared for each use, can be applied once or several times daily. 200ml pack size is for single use only.

To use as a skin disinfectant, as an antiseptic treatment of superficial wounds or burns:

- Apply to the skin undiluted. Apply enough to wet the area to be treated completely but do not allow pools of solution to form under the patient or in the skin folds.
- If applied around the mouth or throat, avoid breathing it in. It should not be swallowed.
- For use as a skin disinfectant, the solution should be applied at least 1 minute before the procedure for areas with very few sweat glands (such as back of the arms) and at least 10 minutes before for areas with many sweat glands such as the hands or feet.

For healthcare professionals use only:

To use as an antiseptic irrigation, or for washes and baths, or as a mucosal antiseptic, including application to the eye see further information in the technical information at the end of this leaflet.

The brown colouration is normal, and shows that it is working properly. Do not use if the solution is not brown.

If you have Videne Antiseptic Solution in a bath or sink you should clean up immediately after use. Videne Antiseptic Solution can generally be washed out of textiles or other materials with warm water and soap; ammonia solution or sodium thiosulphate may be needed if this does not work.

Actions to be taken if swallowed: If you accidentally swallow Videne Antiseptic Solution you should go to your nearest hospital immediately.

4. Possible side effects

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

Skin reactions, which may be delayed, are rare, affecting 1 to 10 users in 10,000. Symptoms include itching, red skin and blisters. Also rarely, after pre-operative disinfection, a pool may form under the patient causing irritation.

Sudden serious allergic reactions, which may be life threatening, occur very rarely, typically affecting less than 1 user in 10,000. Symptoms include swelling of the lips, eyes, throat, tongue and other parts of the body, shortness of breath, wheezing or trouble breathing. Hyperthyroidism (overactive thyroid) may also occur very rarely, especially in susceptible patients.

When used on large wounds or severe burns this may result in changes in the blood chemistry and problems with kidneys (usually detected by a blood test).

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, website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of the 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 of the label. Do not use if the solution is not brown. 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

Videte Antiseptic Solution contains 10% w/w of the active substance iodinated povidone equivalent to 11 mg/ml iodine. The other ingredients are polyoxyl 40 hydrogenated castor oil, citric acid, disodium phosphate anhydrous and purified water.

Videne Antiseptic Solution is a dark reddish brown liquid, supplied in a 200ml HDPE bottle sealed with a plastic screw cap.

MA Holder & Manufacturer:

Ecolab Deutschland GmbH,
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Germany

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The following information is intended for healthcare professionals only:

Dilution of Videne Antiseptic Solution

For antiseptic irrigation, washes and baths, or as a mucosal antiseptic, Videne Antiseptic Solution can be diluted in the following ratios:

- wound irrigation and perioperatively 1:2 to 1:20
- antiseptic washes 1:2 to 1:25

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- antiseptic partial baths approx. 1:25, antiseptic full baths approx. 1:100.
- for eye irrigation dilution should be 1:2 giving a 5% solution

Normal tap water is suitable for dilution. Where conditions requiring isotonicity are desired, physiological saline or Ringer's solution can be used. For application to the eye, dilution with phosphate buffered solutions or balanced salts solution is recommended.

Incompatibilities

Videne Antiseptic Solution may interact with protein and other organic substances.

The treatment area should be irrigated to remove as much blood as possible before using Videne Antiseptic Solution.

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 Antiseptic Solution 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.