

B. PACKAGE LEAFLET

Package leaflet: Information for the patient

Videne 10% w/w Alcoholic Tincture

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 you 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 Alcoholic Tincture in this label-leaflet, contains iodinated povidone as the active substance. It is an antiseptic skin cleanser for use as a quick-drying antiseptic for pre-operative skin disinfection, particularly in orthopaedic surgery. Solutions of iodinated povidone gradually release iodine to kill or stop the growth of micro-organisms (bacteria, fungi, viruses, protozoa, cysts and spores).

2. What you need to know before you use

Do not use:

- On on pre-term and newborn infants.
- 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).
- On broken skin as the alcohol could cause stinging.
- For external use only. Do not swallow

Warnings and precautions

Talk to your doctor or nurse before using Videne Alcoholic Tincture if:

- You are using on large wounds or severe burns as it could product 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.

This medicine contains 24300mg of alcohol (ethanol) in each 100ml which is equivalent to 244mg/g (24.4% w/w). It may cause burning sensation on damaged skin.

Videne Alcoholic Tincture contains the excipient macroglycerol hydroxystearate. This may cause skin reactions.

Other medicines and Videne Alcoholic Tincture

- Talk to your doctor or nurse before using Videne Alcoholic Tincture 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 Alcoholic Tincture if you are pregnant or breast-feeding.

3. How to use

Apply thoroughly to the skin undiluted using a gauze swab. Do not allow pools of solution to form under the patient or in skin folds. There are no special recommendations for the amounts used on children or elderly patients. 200ml pack size is for single use only.

Action to be taken if swallowed:

If Videne Alcoholic Tincture 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, Website: www.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 Alcoholic Tincture contains 10% w/w of active substance iodinated povidone equivalent to 11 mg/ml iodine. The other ingredients are macrogolglycerol hydroxystearate, ethanol 96%, citric acid, anhydrous disodium hydrogen phosphate and purified water.

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

MA Holder & Manufacturer

Ecolab Deutschland GmbH
Ecolab-Allee 1, D-40789,
Germany

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

Incompatibilities

Videne Alcoholic Tincture may interact with protein and other organic substances.

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