Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Videne 10% w/w Alcoholic Tincture

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Iodinated povidone 10% w/w.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous solution.
A dark reddish brown mobile liquid with a characteristic odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Videne 10% w/w Alcoholic Tincture is a broad-spectrum antiseptic for topical application. It is indicated for quick drying pre-operative skin disinfection, particularly in orthopaedic surgery.

4.2 Posology and method of administration

Videne 10% w/w Alcoholic Tincture is applied undiluted to the area to be incised and painted on thoroughly using a gauze swab. The solution may be allowed to dry to form a protective film or may be removed using a sterile gauze swab.

Neonates:
Do not use on neonates, refer to Section 4.3.

Children and Elderly:
There are no special dosage recommendations for children or elderly patients.

Renal Impairment:
Patients with renal impairment should refer to Section 4.4.

4.3 Contraindications

Videne 10% w/w Alcoholic Tincture must never be administered orally, and is contra-indicated in neonates, and during pregnancy and lactation.

Regular or prolonged use should be avoided in patients with thyroid disorders or those receiving lithium therapy.

Hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Care should be taken with known iodine-sensitive subjects, although such people do not normally react to iodinated povidone.

Videne 10% w/w Alcoholic Tincture must not be used on broken skin because of the intense stinging caused by the alcohol present.

The application of povidone-iodine to large wounds or severe burns may produce systemic adverse effects such as metabolic acidosis, hypernatraemia, and impairment of renal function.

4.5 Interaction with other medicinal products and other forms of interactions

It is to be expected that povidone-iodine reacts with protein and various other organic substances such as blood and pus components, for example. This interaction may impair efficacy.

As a result of oxidation, the concomitant application of Videne 10% w/w Alcoholic Tincture and enzymatic wound treatment agents weakens the action of the enzyme components of both drugs. The latter is also true of hydrogen peroxide and taurolidine as well as of disinfectants containing silver (formation of silver iodide).

Videne 10% w/w Alcoholic Tincture must not be used concomitantly or immediately following disinfectants containing mercury (risk of chemical burns due to the formation of mercury iodide).

Videne 10% w/w Alcoholic Tincture must not be used concomitantly with or immediately after the application of octenidine-based antiseptics to the same or adjacent areas as transient dark discolouration can occur at the areas concerned.

In patients receiving concomitant lithium therapy, regular application of Videne 10% w/w Alcoholic Tincture should be avoided as, especially in the case of application of povidone-iodine to extensive areas, larger amounts of iodine may be absorbed. In exceptional cases, this can induce (transient) hypothyroidism. In this special situation, a synergistic effect might also occur as lithium may also induce hypothyroidism.

Effect on diagnostic tests
Due to the oxidising action of povidone-iodine, when patients are undergoing treatment with Videne 10% w/w Alcoholic Tincture various diagnostic agents can give false-positive results (inter alia toluidine and guaiac resin for the determination of haemoglobin or glucose in the stools or urine).

During the application of povidone-iodine uptake of iodine by the thyroid gland may be reduced; this can lead to disturbances in thyroid scanning, PBI (protein-bound iodine) determination and radioiodine diagnostics and make planned radioiodine therapy impossible. A waiting period of at least 1-2 weeks should be observed after discontinuing the povidone-iodine treatment before conducting a new thyroid scan.

4.6 Fertility, pregnancy and lactation

Videne 10% w/w Alcoholic Tincture is not recommended for use during pregnancy because of the possibility of absorption through broken skin and subsequent interference with tests of neonatal thyroid function. Videne 10% w/w Alcoholic Tincture should not be used in neonates or during lactation. Refer to Section 4.3.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

In very rare instances Videne 10% w/w Alcoholic Tincture may produce skin reactions in iodine-sensitive subjects. These reactions subside on cessation of treatment.

=System Organ Class	Very Common (≥1/10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1,000 to < 1/100)	Rare (≥ 1/10,000 to < 1/1,000)	Very Rare (< 1/10,000)	Not known (cannot be estimated from the data available)

Skin and Subcutaneous Tissue Disorders					**Skin irritation**	

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions 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.

4.9 Overdose

In cases where Videne 10% w/w Alcoholic Tincture has been taken orally, gastric lavage with dilute starch mucilage or a 1% solution of sodium thiosulphate must be administered. The electrolyte balance must be corrected and lost fluids replaced.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: D08AG02
Dermatologicals/Antiseptics and Disinfectants/povidone-iodine

Iodinated povidone has antiseptic activity and is used mainly for the treatment of contaminated wounds and pre-operative preparation of skin and mucous membranes. It is considered to be less irritant than iodine.

5.2 Pharmacokinetic properties

Iodinated povidone is slightly absorbed when applied to the skin. Iodides are excreted mainly in the urine, with smaller amounts appearing in the faeces, saliva and sweat.

5.3 Preclinical safety data

Iodinated povidone had a low acute toxicity in both dogs and rats following either oral or intraperitoneal administration. Absorption of iodine through intact skin is low following the application of solutions of iodinated povidone although systemic absorption of iodine is greatly increased if the solutions are applied to broken skin, mucous membranes or are introduced into the cavities of the body. At subcutaneous dose levels of up to 75mg/kg/day, iodinated povidone was non-teratogenic in rabbits following administration to pregnant animals during the period of organogenesis.

Some early *in vitro* studies indicated a possible mutagenic action for iodinated povidone. However, a number of later studies, using *in vitro* and *in vivo* test systems, do not indicate a significant level of mutagenic/genotoxic activity for iodinated povidone. Although conflicting data have been published, there is no convincing evidence to suggest that iodinated povidone adversely affects wound healing. Concentrations of 0.05 and 0.5% iodinated povidone did not cause significant ocular damage when administered into the vitreous cavities of rabbits' eyes. There is some evidence to suggest that iodinated povidone-containing solutions applied to the round window of the chinchilla ear could result in high frequency hearing loss.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Alkyl phenol ether sulphate (ammonium salt)
Industrial Methylated Spirit (95%)
Citric Acid
Anhydrous Disodium Hydrogen Phosphate
Purified Water

6.2 Incompatibilities

Povidone-iodine is incompatible with reducing agents, alkaloid salts, tannic acid, salicylic acid, silver, mercury and bismuth salts, taurolidine and hydrogen peroxide (see also 4.5).

6.3 Shelf life

One year.

6.4 Special precautions for storage

Do not store above 25oC.

6.5 Nature and contents of container

Videne 10% w/w Alcoholic Tincture is packaged in a 500ml HDPE bottle sealed with a plastic screw cap.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Ecolab Deutschland GmbH
Ecolab-Allee 1
D-40789 Monheim am Rhein
Germany

8 MARKETING AUTHORISATION NUMBER

PA1843/002/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23 June 2000
Date of last renewal: 01 May 2008

10 DATE OF REVISION OF THE TEXT

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