Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Videne Antiseptic Solution 10% w/w Cutaneous Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of cutaneous solution contains 10%w/w iodinated povidone, equivalent to 11mg iodine.

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

For once-only use:
Disinfection of intact external skin or as a mucosal antiseptic, for example prior to surgery, biopsies, injections, punctures, blood-taking and bladder catheterisations.

For repeated, time-limited use:
Antiseptic wound treatment (eg, decubitus and varicose ulcers), burns, infected and superinfected dermatoses.

4.2 Posology and method of administration

Videne Antiseptic Solution is intended for topical application either undiluted or diluted.

Used as a disinfectant or an antiseptic for the skin or mucosa, eg, prior to surgery, biopsies, injections, punctures, blood-taking and bladder catheterisations Videne Antiseptic Solution should be applied undiluted.

For the disinfection of skin areas with a sparse distribution of sebaceous glands the exposure time is at least one minute, in skin areas with a dense distribution of sebaceous glands at least 10 minutes. The skin should be kept moist for the entire duration of the exposure time with the undiluted preparation.

For the antiseptic treatment of superficial wounds Videne Antiseptic Solution is applied undiluted to the areas to be treated.

In antiseptic topical therapy of burn wounds, Videne Antiseptic Solution is generally applied undiluted to the areas to be treated.

For antiseptic irrigation, washes and baths Videne Antiseptic Solution can be diluted. The following dilutions are recommended as standard ratios:

- Irrigation within the scope of wound treatment (eg, decubitus, varicose ulcer and gangrene) and perioperative infection prophylaxis 1:2 to 1:20
- Antiseptic washes 1:2 to 1:25
- Antiseptic partial baths approx. 1:25, antiseptic full baths approx. 1:100

Normal tap water is suitable for dilution. Where conditions approximating isotonicity are desired, physiological saline or Ringer's solution can be used.

For application to the eye solutions buffered with phosphate buffer solutions are recommended.

Dilutions must always be freshly prepared and used immediately.

Sufficient Videne Antiseptic Solution must be applied to wet the area to be treated completely. The antiseptic film that forms as it dries can be easily rinsed off with water.

Due to the possibility of skin irritations, when used for preoperative disinfection of the skin avoid pooling of the product under the patient.

In repeated use, the frequency and duration of application depends on the indication for use. Videne Antiseptic Solution, freshly prepared for each use, can be applied several times daily.

Wound treatment should be continued for as long as there are signs of an infection or a marked risk of infection of the wound. Should infection reoccur after discontinuing treatment with Videne Antiseptic Solution, treatment can be resumed.

The brown colouration caused by Videne Antiseptic Solution is a property of the preparation and indicates its efficacy. Considerable decolouration indicates exhaustion of the efficacy of the preparation.

When applying Videne Antiseptic Solution as a bath, etc., iodine may be found in the vicinity in the form of a brown precipitate. Immediate cleaning of the bath is recommended.

As a general rule, Videne Antiseptic Solution can be washed out of textiles and other materials with warm water and soap. In persistent cases, ammonia solution or fixing salt (sodium thiosulphate) may be used; both are available in dispensing pharmacies or drugstores.

Neonates and nursing infants
Videne Antiseptic Solution should only be applied after careful diagnosis and for only extremely limited use for neonates and nursing infants up to the age of 6 months old

Elderly:
Videne Antiseptic Solution should only be applied after careful diagnosis for elderly patients predisposed to hyperthyroidism ie with autonomous adenomas and/or functional automony.

4.3 Contraindications

Videne Antiseptic Solution must not be used:
- in hyperthyroidism or other manifest thyroid diseases;
- in herpetiform dermatitis (Duhring's disease);
- before and after a radioiodine application (until the end of the treatment);
- in known cases of hypersensitivity to iodinated povidone or any of the ingredients of the medication.

4.4 Special warnings and precautions for use

Care must be taken when applying Videne to the oral cavity to avoid the risk of aspiration with consequent pneumonia and other possible respiratory complications.

The product must not be swallowed.

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

Videne Antiseptic Solution should only be applied after careful diagnosis:
–over a prolonged period (>5 days) and on extensive areas (e.g., over 10% of the body surface area), in patients with:

- bland multinodular goitre;
- after patients have been treated for thyroid diseases;
- and in those predisposed to hyperthyroidism i.e. with autonomous adenomas and/or functional automony (especially in elderly patients)

as subsequent iodine-induced hyperthyroidism cannot be completely ruled out. 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 monitored;

– to an extremely limited extent in neonates and nursing infants up to the age of 6 months as the risk of hypothyroidism cannot be completely ruled out. 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.

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 Antiseptic Solution 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 Antiseptic Solution must not be used concomitantly or immediately following disinfectants containing mercury (risk of chemical burns due to the formation of mercury iodide).

Videne Antiseptic Solution 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 Antiseptic Solution 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 Antiseptic Solution 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

Fertility
Reproductive toxicity (safety) is not known.

Pregnancy and Lactation
During pregnancy and the lactation period, Videne Antiseptic Solution – as in all preparations containing iodine – must only be administered following a very careful assessment of the risk/benefit and in extremely limited amounts. After applying Videne Antiseptic Solution thyroid function must be monitored in the child. In the event of hypothyroidism, immediate treatment with thyroid hormones must be carried out until thyroid function returns to (see also Section 4.3 Contraindications).

The accidental oral intake of Videne Antiseptic Solution by the nursing infant as a result of contact with the treated site of the nursing mother’s body must be avoided (see also Section 4.3 Contraindications).

If, due to the nature and extent of the application of Videne Antiseptic Solution, a marked absorption of iodine is to be expected, it must be taken into account that, as a result, the iodine content of the mother's milk may also increase (see also 5.2 Pharmacokinetic properties and 5.3 “Preclinical safety data).

4.7 Effects on ability to drive and use machines

Videne Antiseptic Solution has no influence on the ability to drive and use machines.

4.8 Undesirable effects

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)
Immune System Disorders				Hyper-sensitivity	Anaphylactic reactions	
Metabolic and Nutrition Disorders					Hyper-thyroidism	Metabolic Acidosis Electrolyte disturbance
Skin and Subcutaneous Tissue Disorders				Dependent rubor Skin irritation Pruritus Vesicles		
Renal and Urinary Disorders						Renal Insufficiency
Investigations						Serum osmolarity disturbance

Immune System Disorders:

Rare: Hypersensitivity reactions of the skin.

Very Rare: Anaphylactic reactions

Metabolic and Nutrition Disorders:

Very Rare: An appreciable uptake of iodine can occur with long-term application of Videne Antiseptic Solution to extensive skin, wound or burn areas. Very rarely, in predisposed patients, iodine-induced hyperthyroidism can occur.

Frequency Not Known: Following absorption of larger amounts of povidone-iodine (e.g., in the treatment of burns), the occurrence of (additional) electrolyte and serum osmolarity disturbances as well as severe metabolic acidosis has been described.

Skin and Subcutaneous Tissue Disorders:

Rare: Delayed contact allergy reactions, which can express themselves in the form of pruritus, rubor, vesicles. Irritations of the skin after preoperative disinfection have been reported.

Renal and Urinary Disorders:

Frequency Not Known: Following absorption of larger amounts of povidone-iodine (e.g., in the treatment of burns) renal insufficiency has been described.

Investigations:

Frequency Not Known: Following absorption of larger amounts of povidone-iodine (e.g., in the treatment of burns) serum osmolarity disturbances have been described.

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

a) Intoxication symptoms
Following inadvertent oral intake of large amounts of povidone-iodine, symptoms of acute iodine in-toxication can manifest such as abdominal pain and cramps, nausea, vomiting, diarrhoea, dehydration, drop in blood pressure (persistent), tendency to collapse, epiglottitis, haemorrhagic diathesis (mucosal membranes and kidneys), cyanosis, renal damage (acute tubular necroses up to anuria [after 1-3 days]), parasthesias, fever and pulmonary oedemas. Following long-term excessive intake of iodine, hyperthyroidism, tachycardia, restlessness, tremor and headache can occur as symptoms.

In the literature, symptoms of intoxication after the intake of more than 10 g povidone-iodine were reported.

b) Therapeutic measures to treat cases of intoxication
Immediate administration of foodstuffs containing starch and protein, eg, corn flour stirred into milk or water, or gastric lavage with 1% sodium thiosulphate solution or starch suspension.

After absorption has already taken place toxic serum iodine concentrations can be reduced effectively by peritoneal dialysis or haemodialysis.

Thyroid function must be monitored carefully clinically to rule out or identify at an early stage any possible iodine-induced hyperthyroidism.

Further therapy is carried out as required to manage other possible existing symptoms such as metabolic acidosis and renal dysfunction, for example.

c) Treatment of iodine-induced hyperthyroidism
The treatment of iodine-induced hyperthyroidism (possible side effect in predisposed patients, see also 4.3 Contraindications) is conducted as clinically indicated. Mild forms may require no treatment, pronounced forms may require anti-thyroid medical therapy (which is, however, effective only after a delay). In the most severe cases (thyrotoxic crisis), intensive therapy, plasmapheresis or thyroidectomy may be required.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Dermatologicals/Antiseptics and Disinfectants/povidone-iodine
ATC Code: D08AG02
The povidone-iodine complex is active at pH values between 2 and 7. The microbiocidal effect is based on the fraction of free, non-complex-bound iodine released in water-based ointments or solutions from the povidone-iodine complex as defined in an equilibrium reaction. The povidone-iodine complex thus to some degree represents an iodine depot, which releases elementary iodine protractedly and in this way guarantees a steady concentration of the efficacious free iodine.
As a result of the binding to the povidone complex, the topical irritant properties of iodine are reduced compared to the alcoholic iodine solutions.

The free iodine reacts as a strong oxidising agent principally at the molecular level with unsaturated fatty acids as well as readily oxidisable SH or OH groups of the amino acids in enzymes and structural building blocks of microorganisms. This non-specific mode of action explains the comprehensive efficacy of povidone-iodine against a wide spectrum of human pathogenic microorganisms, eg, Gram-positive and Gram-negative bacteria, mycobacteria, fungi (particularly *Candida*), numerous viruses and some protozoa. Bacterial spores and several species of virus are, in general, inactivated only after longer exposure to an adequate extent.

Specific primary forms of resistance against povidone-iodine and also the formation of secondary forms of resistance in long-term application are not anticipated.

5.2 Pharmacokinetic properties

After applying povidone-iodine the possibility of iodine absorption must be considered. This depends upon the nature and duration of treatment as well as the amount applied. Following application to the intact skin only very small amounts of iodine are absorbed. Marked absorption of iodine can occur after long-term application of povidone-iodine-containing medication to mucosal membranes, extensive skin, wound or burn surfaces and especially after irrigation of body orifices. An elevated iodine concentration in the blood as a result of this is generally transient. In people with a healthy thyroid gland, the increased availability of iodine does not lead to clinically relevant changes in thyroid hormone status. If iodine metabolism is normal, iodine elimination via the kidneys is enhanced.

The absorption of povidone and, to a greater extent, the renal elimination of povidone is dependent on the average molecular weight of the mixture. Above a molecular weight of 35,000 to 50,000 retention within the reticulohistiocytic system is to be expected. The accumulation of povidone in the body and other changes which may be seen following intravenous or subcutaneous administration of povidone-containing medicaments do not occur after topical application of povidone-iodine.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of acute toxicity, chronic toxicity and mutagenicity. No long-term carcinogenic studies on povidone-iodine are available.

Due to the ability of iodine to cross the placental barrier and the sensitivity of the foetus towards pharmacological doses of iodine, the potential absorption of large quantities of iodine must be avoided during pregnancy. Iodine accumulates to a greater extent in the milk compared with the serum so povidone-iodine should only be applied during the lactation period after careful assessment of the risk/benefit.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Alkyl phenol ether sulphate (ammonium salt)
Glycerol
Citric acid
Disodium hydrogen phosphate dodecahydrate
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 Interactions with other medicaments and other forms of interaction).

6.3 Shelf life

2 years

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Videne Antiseptic Solution 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

PA1843/002/002

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10 DATE OF REVISION OF THE TEXT

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