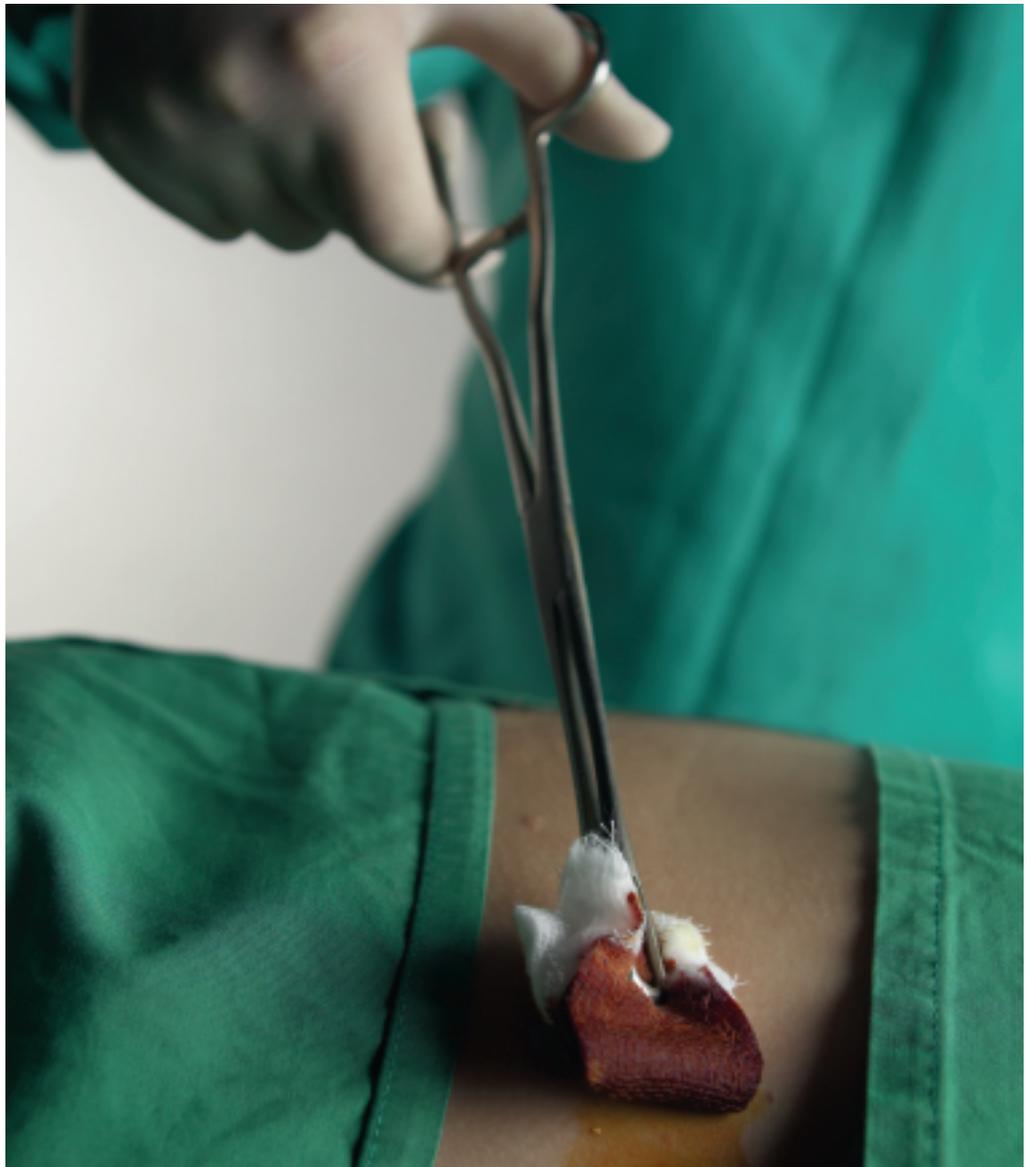


Videne®

Povidone-Iodine 10%w/w

Skin disinfection



- High quality Povidone-Iodine solutions
- Broad spectrum efficacy
- Standard concentrations

Health Care

Videne®

Povidone-Iodine 10%w/w

Skin disinfection



Why use Videne?

Formulated to standard concentrations making Videne simple to integrate into existing procedures

High quality and cost effective

Povidone-Iodine offers activity against a broad range of bacteria, viruses, fungi and some bacterial spores^{1,2}

Povidone-Iodine preparations provide a clear colour delineation of areas disinfected

Areas of use

Videne Antiseptic Solution is an aqueous solution for use as a pre-operative skin disinfectant.

Videne Alcoholic Tincture is for use as a pre-operative skin disinfectant, especially useful where quick drying is required.

Product Specification

Videne® Antiseptic Solution - An aqueous antiseptic solution containing 10% w/w Povidone-Iodine which gives 1% w/w available iodine.

Videne® Alcoholic Tincture - An alcoholic solution containing 10% w/w Povidone-Iodine which gives 1% w/w available iodine.

Ordering Information

Description	Unit Contents	Outer Size	Re-order Code
Videne Antiseptic Solution	500ml	12	469920
Videne Alcoholic Tincture	500ml	12	469912
Pump Dispenser		1	408409
Wire Elbow Dispenser		1	408412
Wall Mounted Dispenser		1	409634

Summary of Product Characteristics

Videne Antiseptic Solution

Trade Name of the Medicinal Product: Videne Antiseptic Solution. **Qualitative and Quantitative Composition:** Povidone-iodine 10% w/w. **Pharmaceutical Form:** Topical Solution. **Clinical Particulars - Therapeutic Indications:** Videne Antiseptic Solution is a broad-spectrum antiseptic for topical use. It may be used whenever an effective antiseptic is required for the skin eg in casualty work or for pre-operative skin preparation. It will give a colour delineation to the skin which effectively indicates which areas of the skin remain antiseptic. **Posology and Method of Administration:** Videne Antiseptic Solution is applied undiluted to the skin in the area to be disinfected painting on with a gauze swab. It can then be removed with sterile gauze swabs. Videne Antiseptic Solution may also be applied on impregnated gauze swabs which are then held on to the skin with bandages. There are no special dosage recommendations for children or elderly patients. **Contra-indications:** Videne Antiseptic Solution must never be administered orally. **Special Warning and Precautions for Use:** Care should be taken with known iodine-sensitive subjects, although such people do not normally react to povidone-iodine. **Interactions with Other Medicinal Products and Other Forms of Interaction:** None stated. **Pregnancy and Lactation:** Videne Antiseptic Solution 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. **Effects on Ability to Drive and Use Machines:** None stated. **Undesirable Effects:** In very rare instances Videne Antiseptic Solution may produce skin reactions in iodine-sensitive subjects. These reactions subside on cessation of treatment. **Overdose:** In cases where Videne Antiseptic Solution 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. **Pharmacological Properties - Pharmacodynamic Properties:** Povidone-iodine 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. **Pharmacokinetic Properties:** Povidone-iodine 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. **Preclearance Safety Data:** Povidone-iodine 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 povidone-iodine although systemic absorption of iodine is greatly increased if the solutions are applied to broken skin, mucous membranes or are introduced into cavities of the body. At subcutaneous dose levels of up to 75mg/kg/day, povidone-iodine 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 povidone-iodine. 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 povidone-iodine. Although conflicting data have been published, there is no convincing evidence to suggest that povidone-iodine adversely affects wound healing. Concentration of 0.05 and 0.5% povidone-iodine did not cause significant ocular damage when administered into the vitreous cavities of rabbits' eyes. There is some evidence to suggest that povidone-iodine-containing solutions applied to the round window of the chinchilla ear could result in high frequency hearing loss. **Pharmaceutical Particulars - List of Excipients:** Alkyl Phenol Ether Sulphate (Ammonium Salt), Glycerol, Citric Acid Di-sodium Phosphate Anhydrous, Purified Water BP. **Incompatibilities:** None stated. **Shelf Life:** 24 months. **Special Precautions for Storage:** Store below 30°C in a dry place, protected from light. **Nature and Contents of Container:** Videne Antiseptic Solution is packaged in a 500ml HDPE bottle sealed with a plastic screw cap. **Instructions for Use and Handling:** None stated. **Legal Category:** [P] Cost: Unit price £1.85. **Marketing Authorisation Holder:** Ecolab Ltd trading as Adams Healthcare, Lotherton Way, Garforth, Leeds, LS25 2JY. **Marketing Authorisation Number:** PL 04509/0041. **Date of Preparation:** 1 March 2003.

Videne Alcoholic Tincture

Trade Name of the Medicinal Product: Videne Alcoholic Tincture. **Qualitative and Quantitative Composition:** Povidone-iodine 10% w/w. **Pharmaceutical Form:** Topical Solution. **Clinical Particulars - Therapeutic Indications:** Videne Alcoholic Tincture is a broad-spectrum antiseptic for topical application. It is indicated for quick-drying pre-operative skin disinfection, particularly in orthopaedic surgery. **Posology and Method of Administration:** Videne 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. There are no special dosage recommendations for children or elderly patients. **Contra-indications:** Videne Alcoholic Tincture must never be administered orally. **Special Warnings and Precautions for Use:** Care should be taken with known iodine-sensitive subjects, although such people do not normally react to povidone-iodine. Videne Alcoholic Tincture must not be used on broken skin because of the intense stinging caused by the alcohol present. **Interactions with other Medicaments and Other Forms of Interaction:** None stated. **Pregnancy and Lactation:** Videne 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. **Effects on Ability to Drive and Use Machines:** None stated. **Undesirable Effects:** In very rare

instances Videne Alcoholic Tincture may produce skin reactions in iodine-sensitive subjects. These reactions subside on cessation of treatment. **Overdose:** In cases where Videne 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. **Pharmacological Properties - Pharmacodynamic Properties:** Povidone-iodine has antiseptic activity and is used mainly for the treatment of contaminated wounds and preparation of pre-operative skin and mucous membranes. It is considered to be less irritant than iodine. **Pharmacokinetic Properties:** Povidone-iodine 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. **Preclearance Safety Data:** Povidone-iodine 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 povidone-iodine although systemic absorption of iodine is greatly increased if the solutions are applied to broken skin, mucous membranes or are introduced into cavities of the body. At subcutaneous dose levels of up to 75mg/kg/day, povidone-iodine 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 povidone-iodine. 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 povidone-iodine. Although conflicting data have been published, there is no convincing evidence to suggest that povidone-iodine adversely affects wound healing. Concentration of 0.05 and 0.5% povidone-iodine did not cause significant ocular damage when administered into the vitreous cavities of rabbits' eyes. There is some evidence to suggest that povidone-iodine-containing solutions applied to the round window of the chinchilla ear could result in high frequency hearing loss. **Pharmaceutical Particulars - List of Excipients:** Alkyl Phenol Ether Sulphate (ammonium salt), Industrial Methylated Spirit 95%, Citric Acid, Di-sodium Phosphate, Anhydrous, Purified Water. **Incompatibilities:** None stated. **Shelf Life:** 24 months. **Special Precautions for Storage:** Store below 20°C in a dry place, protected from light. **Nature and Contents of Container:** Videne Alcoholic Tincture is packaged in a 500 ml HDPE bottle sealed with a plastic screw cap. **Instructions for Use/Handling:** None stated. **Product Category:** [P] Cost: Unit price £1.70. **Marketing Authorisation Holder:** Ecolab Ltd trading as Adams Healthcare, Lotherton Way, Garforth, Leeds LS25 2JY. **Marketing Authorisation Number:** PL 04509/0040. **Date of Preparation:** 1 March 2003.

References

1. Martindale. The Extra Pharmacopoeia, 31st edition (1996) 1143-4
2. McLure AR and Gordon J. In-vitro evaluation of povidone-iodine and chlorhexidine against methicillin resistant Staphylococcus aureus. J. Hospital Infection (1992) 21, 291-299

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