



SINGLE USE PRE-OPERATIVE SKIN DISINFECTION

Videne™ Antiseptic Solution 10% w/w Cutaneous Solution

Povidone iodine 10% w/w

SKIN, MUCOUS MEMBRANE AND WOUND ANTISEPTIC

Disinfection of intact external skin or as a mucosal antiseptic prior to surgery, biopsies, injections, punctures, blood-taking and bladder catheterisations.

Antiseptic wound treatment (eg, decubitus and varicose ulcers), burns, infected and superinfected dermatoses.

- Aqueous solution for disinfection of mucous membranes and where alcohol or chlorhexidine are not suitable
- Skin staining to provide enhanced visualisation of prepared area
- Single use medicinal product



Videne™ Antiseptic Solution

10% w/w Cutaneous Solution

Skin, mucous membrane and wound antiseptic.

BROAD SPECTRUM EFFICACY

Povidone iodine is extremely effective against a wide range of gram positive and gram negative bacteria, fungi and bacterial spores.^{1,2}

SKIN STAINING

The brown stain from povidone iodine provides enhanced visualisation of the prepared area.

RECOMMENDED BY NICE GUIDANCE NG125

NICE recommends an aqueous solution of povidone iodine where alcohol based solution or chlorhexidine are not suitable.³

PACKAGING AND ORDERING INFORMATION

PRODUCT	PACKAGING UNIT	ORDER CODE
Videne Antiseptic Solution	24 x 200ml	3131392

SUMMARY OF PRODUCT CHARACTERISTICS

Name of the Medicinal Product: Videne Antiseptic Solution 10% w/w cutaneous solution. **Active ingredient:** Iodinated Povidone 10% w/w.

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. **Undesirable Effects:** 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 (eg, in the treatment of burns), the occurrence of (additional) electrolyte and serum osmolality 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 (eg, in the treatment of burns) renal insufficiency has been described. Investigations: Frequency Not Known: Following absorption of larger amounts of povidone-iodine (eg, in the treatment of burns) serum osmolality 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 the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard. **Contraindications:** Videne Antiseptic Solution must not be used: in hyperthyroidism or other manifest thyroid diseases; in herpetic dermatitis (Dühring'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. **Warnings:** 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 (eg, 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 autonomy (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. **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 the normal. 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. 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. **Posology And Method Of Administration:** Videne Antiseptic Solution is intended for topical application either undiluted or diluted. 200 ml pack size is for single use only. 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 sebaceous 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 i.e. with autonomous adenomas and/or functional autonomy. **Marketing Authorisation Holder:** Ecolab Ltd, Unit 1, Wernddu Court, Caerphilly CF83 3SG, United Kingdom. **License Number:** UK: PL04509/0029. **Sales Status:**  Please read carefully the instructions on the SPC and on the label leaflet. **Date of Revision of the Text:** October 2023.

INSTRUCTIONS FOR USE

Refer to the Summary of Product Characteristics.

This product is applied topically. 200 ml pack size is for single use only.

Antiseptic for the skin or mucosa

Apply undiluted. The skin or mucosa should be kept moist for the entire duration of the exposure time with the undiluted preparation:

- For skin with a low number of sebaceous glands: at least 1 minute.
- For skin with a high number of sebaceous glands: at least 10 minutes.

Antiseptic treatment of superficial wounds and topical therapy of burn wounds

Apply undiluted to the areas to be treated.

Antiseptic irrigation, washes and baths

Dilute Videne Antiseptic Solution in accordance with the dilution ratios from the Summary of Product Characteristics.

TRAINING AND SUPPORT

Ecolab's national team of Clinical Implementation Specialists are available to support with all training and educational needs. Please contact your local Ecolab representative for further information.

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, 291-2993.
- 3 NICE guideline [NG125] Surgical site infections: prevention and treatment, April 2019

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