SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Povidone Iodine 5% w/v Eye drops, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Povidone Iodine 5% w/v equivalent to 50 mg/ml

Each 20 ml unit dose container contains 1000 mg Iodinated Povidone (50 mg/ml)

Excipient(s) with known effect

Disodium phosphate anhydrous 0.73 mg/ml (see section 4.8)

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Sterile eye drops, solution

Dark brown coloured solution

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Povidone Iodine 5% w/v eye drops, solution is indicated for cutaneous peri-ocular and conjunctival antisepsis prior to ocular surgery to support post-procedural infection control.

4.2 Posology and method of administration

For external use only.

The outer surface of the product container is not sterile. Use of the container in a sterile field should be avoided.

Posology

Adults (including the elderly)

Apply topically to the area around the eyes. Instil the solution onto the cornea, conjunctiva and conjunctival sacs and leave for two minutes before rinsing. See "Method of Administration" for further details.

Paediatric population

No available data.

Method of administration

- Wash hands thoroughly before use.
- Twist off the cap of the single-dose container to open it, and empty the contents into a sterile container.
- Saturate a sterile cotton swab or sterile wadding with solution and prepare the peri-ocular areas, cheeks and forehead.
- Using a sterile syringe or dropper, gently instil the solution onto the cornea, conjunctiva and conjunctival sacs.
- Allow the solution to spread, by asking the patient to close their eyes and roll their eyes around.
- Wait for two minutes then irrigate thoroughly with sterile saline 0.9% w/v solution until the characteristic colour of the iodine solution disappears.
- After use the remaining solution should be discarded.

4.3 Contraindications

This medicinal product must not be used in the following situations:

- Hypersensitivity to iodinated povidone, to iodine or to any of the excipients listed in section 6.1;
- In new-born babies under 1 month of age;
- Povidone Iodine 5% w/v eye drops, solution is contraindicated for intra-ocular or peri-ocular injection;
- Concomitant use of topical agents containing mercury derivatives.

4.4 Special warnings and precautions for use

Special warnings

For ophthalmic use only.
There is no experience of ocular instillation, other than for pre-procedural antisepsis. The use of Povidone Iodine 5% w/v eye drops, solution is restricted to cutaneous-conjunctival surface antisepsis ONLY.

Repeated applications of povidone-iodine to ocular surface related to long term ophthalmic therapy with intravitreal injections may result in tear film abnormalities or aggravate existing tear film abnormalities. Patients with dry eye syndrome should be monitored for any exacerbation of their condition and treated appropriately.

Precautions for use

After the medicinal product has been left in contact with the cornea, conjunctiva and conjunctival sacs for two minutes, flush thoroughly with sterile 0.9% sodium chloride solution.

Concomitant use with topical ophthalmic formulations containing mercury-based preservatives is to be avoided.

Povidone Iodine 5% w/v eye drops, solution should be used with caution in patients suffering from thyroid dysfunction development. Monitoring of thyroid function should be considered, particularly during regular repeated use of the medicinal product.

Cross-reactions with iodinated contrast agents have not been reported.

Use with caution in all circumstances that may favour systemic passage, especially in children under 30 months of age.

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant or subsequent use with other antiseptic agents should be avoided, because of the potential for interference (antagonism, inactivation).

Special caution is needed in relation to iodine incompatibilities. In particular, do not use at the same time a mercury-based derivative: the combination iodine/mercury-based preservatives must be avoided, due to the risk of caustic compounds formation.

Particularly, special care must be taken in relation to the mercurial preservatives used in many ophthalmic preparations.

When administered at volumes greater than those arising from single ocular instillation, povidone iodine may interfere with thyroid function tests.

Povidone iodine is unstable at alkaline pH and is inactivated by sodium thiosulphate.

The povidone iodine complex is active at pH values between 2.0 and 7.0. It is possible that the complex may react with certain proteins and certain unsaturated organic compounds, reducing its effectiveness.

The concomitant use of an enzyme-based wound treatment causes a decrease in the effect of the two treatments.

4.6 Fertility, pregnancy and lactation

Pregnancy

Animal studies have not shown teratogenic effects. Given the absence of teratogenic effects in animals, malformation effects are not expected in humans (see section 5.3).

Currently, relevant clinical data is not sufficiently available to assess the potential malformation impact of povidone iodine when it is administered within the first trimester of pregnancy. The foetal thyroid begins to accumulate iodine around the 14th week of amenorrhoea.

No effects during pregnancy are anticipated, since systemic exposure to iodine is negligible. Povidone Iodine 5% w/v eye drops, solution can be used during pregnancy.

In pregnant or breastfeeding women an alternative form of antisepsis should be considered if repeated use is anticipated.

Breast-feeding

No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to iodine is negligible.

Fertility

No effects on fertility are anticipated, since systemic exposure to iodine is negligible.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

The most serious adverse reaction that occurs with Povidone Iodine 5% w/v eye drops, solution is hypersensitivity reaction.

Adverse events are categorized by frequency as follows:

- 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 available data)

Immune System Disorders:
Not known: hypersensitivity, anaphylactic reactions (urticaria, Quincke's oedema, anaphylactic shock and anaphylactoid reaction).

Endocrine Disorders:
Not known: Regular and prolonged application may lead to toxic levels of iodine likely to develop abnormal thyroid function, particularly in pre-term infants and neonates. Exceptional cases of hypothyroidism have been reported.

Eye disorders:
Not known: conjunctival hyperemia, superficial punctate keratitis, eye irritation, superficial punctate epitheliopathy, keratoconjunctivitis sicca, residual yellow coloration of the conjunctiva.

Cases of corneal calcification have been reported very rarely in association with the use of phosphate containing eye drops in some patients with significantly damaged corneas.

Skin and subcutaneous tissue disorders
Not known: contact dermatitis (with such symptoms as erythema, blisters, itching), angioedema, cases of reversible, transient brown coloration of the skin have been reported.

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 at wwww.mhra.gov.uk/yellowcard or search for 'MHRA Yellow Card' in the Google Play or Apple App Store.

4.9 Overdose

An ocular overdose of Povidone Iodine 5% w/v eye drops, solution can be washed out of the eye with saline or water.
Accidental ingestion may cause iodine resorption and lead to abdominal cramps, bloody diarrhoea, vomiting, shock and medium or long-term oesophageal constrictions. A massive overdose may have serious or fatal consequences.

Treatment
Do not perform gastric lavage. Give the patient milk to drink, administer a starch solution (15 – 20 g in 500 ml water), sodium thiosulphate orally (100 ml in 1% solution). If necessary, admit to intensive care.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Ophthalmologicals; anti-infectives
ATC code: S01AX18
Broad-spectrum antiseptic, bactericidal, virucidal and fungicide.
Antiseptic group: Halogen oxidant (iodophore).

Mechanism of action
Povidone iodine is an iodophore that has an established use as a broad-spectrum antiseptic, mainly for the treatment of contaminated wounds and for the preoperative preparation of the skin, mucous membranes and the ocular surface. The organic complex contains approximately 10% of active available iodine.

Its spectrum of activity is iodine which gradually and slowly released exerts:
- bactericidal effect in less than 5 minutes in vitro, for all bacteria,
- fungicide effect for yeasts and filamentous fungi.

Solutions of povidone iodine gradually release iodine to exert an antimicrobial effect against bacteria, fungi, viruses, and spores. Although povidone iodine is less potent than preparations containing free iodine, it is also less toxic.

Organic materials (proteins, serum and blood) reduce the activity of free iodine, the active form of the medicinal product. Iodophores are unstable at alkaline pH.

Pharmacodynamic effects
Povidone iodine is a complex of the polymer polyvinylpyrrolidone (povidone) with iodine which, after application, continues to deliver iodine to the ocular surface over the short time that the solution is in contact with the eye.

After application, exposure of the ocular surface to iodine arises from the presence of free iodine in solution, and iodine bound to the polymer, which serves as a reservoir. As the preparation comes in contact with the eye, more and more iodine dissociates from the polymer.
Mechanisms of resistance
There are no reports of bacterial cross-resistance to antibiotics arising from exposure to povidone iodine, or iodine, or of co-resistance due to any known genetic linkage of resistance determinants.

There are limited reports of contamination of iodophores with Pseudomonas species, in nutrient restricted environments, such as hospital waste water, indicating that resistance to povidone-iodine can occur. However, this is of limited relevance to the use of povidone iodine in ocular antisepsis.

5.2 Pharmacokinetic properties

The available iodine in iodinated povidone is able to cross the conjunctival barrier to a limited extent. At the concentration used, the potential for systemic exposure to iodine is very low.

Conjunctival and peri-ocular sterilisation with Iodinated Povidone (1.25% or 10%) results in increased urinary elimination of iodide. Elimination is almost exclusively by the renal route. Povidone alone is unlikely to be absorbed systemically.

5.3 Preclinical safety data

Preclinical data from safety pharmacology studies, repeated dose toxicity tests and mutagenicity studies did not provide evidence of a particular risk to humans. Animal studies did not show any teratogenic effects.

In oral sub-acute and chronic toxicity studies, including rat studies, the only effects observed after discontinuation of povidone-iodine were in most cases transient and dose-dependent increases in serum iodine-bound protein and nonspecific histopathological changes in the thyroid gland.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol
Nonoxynol 9
Disodium phosphate anhydrous
Citric acid monohydrate
Sodium chloride
Sodium hydroxide
Purified water

6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products.

Due to the risk of formation of caustic compounds, do not use with ophthalmic preparations containing mercuric based preservatives, for example thiomersal.

Iodine is an oxidant, which can lead to chemical incompatibilities with other substances.

Povidone iodine is inactivated or becomes unstable in the presence of sodium thiosulphate, heat, light or alkaline pH.

6.3 Shelf life

Unopened: 2 years

Once opened: use immediately, discard after first use.

6.4 Special precautions for storage

Do not store above 25 °C.

Store in the original container.

For single use only. Discard any remaining solution.

6.5 Nature and contents of container

A sealed 20 ml high density polyethylene (HDPE) blow-fill-sealed single dose container with a twist and pull off cap.
Pack size: 4 x 20 ml single dose containers in a carton.

6.6 Special precautions for disposal

For single use only. Discard immediately after first use.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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