Minims Povidone Iodine 5% w/v Eye Drops, Solution

Summary of Product Characteristics Updated 14-Nov-2017 | Bausch & Lomb U.K Limited

1. Name of the medicinal product

Minims® Povidone Iodine 5% w/v eye drops, solution

2. Qualitative and quantitative composition

Each single dose container provides 20 mg of Iodinated Povidone in 0.4 ml of solution. One milliliter of solution contains 50 mg Iodinated Povidone

Excipient with known effect: disodium phosphate anhydrous (see section 4.8).

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Eye drops, solution

Deep brown-red coloured solution.

4. Clinical particulars

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Posology

Adults (including the elderly)

Instill two to three drops of the solution onto the eye / eyes and leave for two minutes. See “Method of Administration” for further details.

Paediatric population

The adult dose may be used in neonates, infants, children and adolescents

Method of administration:

- Wash hands thoroughly before use.

- Clean the area around the eyes with a sterile cotton swab

- Twist off the cap of the container to open it

- Do not touch the eye with the single-dose container nozzle.

- Gently instill 2 to 3 drops of the solution onto the eye / eyes

- Allow the solution to spread, by asking the patient to close their eyes and roll their eyes around

- Leave the drops on the eye / eyes for two minutes before rinsing: Using a suitable syringe, irrigate the eye / eyes thoroughly with sterile saline 0.9% w/v solution until the characteristic colour of the iodine solution disappears

4.3 Contraindications

- Hypersensitivity to iodinated povidone, to iodine or to any of the excipients listed in section 6.1

- Minims® Povidone Iodine 5% w/v eye drops, solution is contraindicated for intra-ocular or peri-ocular injection

- Concomitant use with topical ophthalmic formulations containing mercury-based preservatives (see section 4.5)

- Pre-term neonates

4.4 Special warnings and precautions for use

For ophthalmic use only.

There is no experience of ocular instillation, other than for pre-operative antisepsis.

The use of Minims® Povidone Iodine 5% w/v eye drops, solution is restricted to pre-operative ocular antisepsis ONLY.

After two minutes' contact with the conjunctival surface, the product should be thoroughly rinsed off using sterile saline solution.

4.5 Interaction with other medicinal products and other forms of interaction

Do not use with other medicines that are intended for ocular administration, including other antimicrobial agents, because of the potential for antagonism or inactivation of povidone iodine.

In particular, concomitant use with formulations containing mercury-based preservatives (which may be present in some ophthalmic medicines) must be avoided, due to the risk of formation of caustic compounds.

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

4.6 Fertility, pregnancy and lactation

Pregnancy

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

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 occur with Minims® 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)

Eye disorders:

Rare: conjunctival hyperemia, superficial punctuate keratitis

Not known: residual yellow coloration of the conjunctiva, cytotoxicity on mucous membranes and deep tissue, reversible transient brown coloration (which can be removed with water).

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.

Immune System Disorders:

Very rare: hypersensitivity reactions (urticaria, Quincke's oedema, anaphylactic shock and anaphylactoid reaction) with products containing povidone.

Paediatric population

Endocrine Disorders:

Not known: hypothyroidism in neonates.

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:

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

4.9 Overdose

An overdose of Minims® Povidone Iodine 5% w/v eye drops, solution can be washed out of the eye with saline or water.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Ophthalmologicals; anti-infectives

ATC code: S01AX18

Broad-spectrum antiseptic, bactericidal, virucidal and ungicide. 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 loose complex contains approximately 10% of active available iodine.

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. Iodophor**e**s 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

Non-clinical data reveal no special hazard for humans. Effects in non-clinical studies were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use.

Microbiological data: See Section5.1.

Environmental Risk Assessment (ERA)

At the concentrations present in the Eye Drops and at the quantities used, povidone iodine and available iodine do not present any risks to the environment. Assessment of the potential for bioaccumulation has concluded that the potential for persistence, bioaccumulation potential or toxicity (PBT) is very low.

6. Pharmaceutical particulars

6.1 List of excipients

- Glycerol
- Nonoxinol 9
- Disodium phosphate anhydrous
- Citric acid monohydrate
- Sodium chloride
- Sodium hydroxide (for pH adjustment)

- 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: 18months

When stored unrefrigerated at below 25°C: 1month (see section 6.4)

Once opened – use immediately. Discard immediately after first use.

6.4 Special precautions for storage

Store between 2°C and 8°C.

Store in the original package to protect from light.

The product may be stored without refrigeration at not more than 25°C for up to one month.

6.5 Nature and contents of container

A sealed polypropylene single-dose container fitted with a twist and pull off cap marked with “PVI 5.0”.

Each single-dose container provides 0.4 ml of solution and is overwrapped in a polyethylene sachet. Pack size: 20 x 0.4 ml single dose containers in a carton.

6.6 Special precautions for disposal and other handling

For single use only. Discard immediately after first use.

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

7. Marketing authorisation holder

Bausch & Lomb U.K. Ltd

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KT2 6TN

8. Marketing authorisation number(s)

PL 03468/0020

9. Date of first authorisation/renewal of the authorisation

07/12/2012

10. Date of revision of the text

26/10/2017

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