

# Summary of Product Characteristics

## 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 0.75 mg/ml (0.03 mg in each drop) ( 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 antiseptics prior to ocular surgery and/or intravitreal injection to support post-procedural infection control.

### 4.2 Posology and method of administration

#### Posology

##### *Adults (including the elderly)*

Instill 2 to 3 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 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 single-dose 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

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

### 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 Minims 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 conjunctiva and conjunctival sacs for two minutes, flush thoroughly with sterile 0.9 % NaCl solution.

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

Minims Povidone Iodine should be used with caution in patients suffering from thyroid dysfunction and in elderly patients, who are at increased risk of 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. Hypersensitivity (anaphylactoid reactions) to iodinated contrast agents or anaphylactic reaction to shellfish are not contraindications for Minims Povidone Iodine 5% w/v eye drops administration.

## **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.

## **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 14<sup>th</sup> week of amenorrhoea.

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.

In pregnant or breastfeeding women an alternative form of antisepsis should be considered if multiple repeat injections requiring conjunctival and periorbital application are 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 occur with Minims Povidone Iodine 5% w/v eye drops, solution is hypersensitivity reaction.

Adverse events are categorized by frequency as follows:

- Very common ( $\geq 1/10$ )
- Common ( $\geq 1/100$  to  $< 1/10$ )
- Uncommon ( $\geq 1/1,000$  to  $< 1/100$ )
- Rare ( $\geq 1/10,000$  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 HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

**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 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 non-specific histopathological changes in the thyroid gland.

# **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: 18 months

When stored unrefrigerated at below 25°C: 1 month (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 0.5 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 Ireland Limited  
3013 Lake Drive  
Citywest Business Campus  
Dublin 24  
D24 PPT3  
Ireland

## 8 MARKETING AUTHORISATION NUMBER

PA23259/018/001

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14<sup>th</sup> December 2012

Date of last renewal: 3<sup>rd</sup> October 2017

**10 DATE OF REVISION OF THE TEXT**

November 2022