SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

OFTASTERIL 50 MG/ML
Eye Drops, Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each single dose container provides 200 mg of Iodinated Povidone in 4.0 ml of solution. One milliliter of solution contains 50 mg Iodinated Povidone.

Excipient with known effect:

This medicine contains 1.5 mg dibasic sodium phosphate dodecahydrate in each milliliter, thus each container of 4 ml contains 6 mg dibasic sodium phosphate dodecahydrate (see section 4.8).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye Drops, Solution

Clear, red-brown solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

OFTASTERIL 50 MG/ML is indicated for the preparation of the surgical field (eyelids, eyelashes and cheeks) and irrigation of the ocular surface (cornea, conjunctiva and palpebral fornices).

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.

- OFTASTERIL 50 MG/ML 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 OFTASTERIL 50 MG/ML 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.

OFTASTERIL 50 MG/ML 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 OFTASTERIL 50 MG/ML 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^{th} week of amenorrhoea.

No effects during pregnancy are anticipated, since systemic exposure to iodine is negligible. OFTASTERIL 50 MG/ML 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

OFTASTERIL 50 MG/ML is not intended for use outside of a hospital or clinic and does not affect the ability to drive or use machines.

Driving and/or operations of machines after surgical procedures should be assessed by the physician.

4.8 Undesirable effects

The most serious adverse reaction that occur with OFTASTERIL 50 MG/ML 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. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form: https://sideeffects.health.gov.il/.

4.9 Overdose

An overdose of OFTASTERIL 50 MG/ML 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

Glycerine

Polysorbate 20

Sodium chloride

Dibasic sodium phosphate dodecahydrate

Sodium hydroxide

Potassium iodate

Citric acid monohydrate

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

The expiry date of the product is indicated on the packaging materials.

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

6.4 Special precautions for storage

Do not store above 25°C.

Store in the original package to protect from light.

6.5 Nature and contents of container

Cardboard box containing 1 brown low density polyethylene sterile, single-use bottle of 4.0 ml eye drops, solution.

The bottle is closed by a polyethylene dropper and a polypropylene screw cap.
The bottle is contained in a double PE/PET sterile sachet.

6.6 Special precautions for disposal

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 MANUFACTURER

Alfa Intes Industria Terapeutica Splendore S.R.L

Via Fratelli Bandiera 26 Casoria Naples, Italy 80026.

8 MARKETING AUTHORISATION HOLDER

K.S. Kim International (SK- Pharma) Ltd.,
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9 MARKETING AUTHORISATION NUMBER(S)

180-30-37848

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