

Package leaflet: Information for the patient

Povidone iodine

5% w/v eye drops solution

povidone, iodinated

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Povidone iodine is and what it is used for
2. What you need to know before you use Povidone iodine
3. How to use Povidone iodine
4. Possible side effects
5. How to store Povidone iodine
6. Contents of the pack and other information

1. What Povidone iodine is and what it is used for
Povidone iodine Eye Drops Solution contains the active substance povidone iodine which belongs to the group of antimicrobial and antiseptic medicines and which works by killing bacteria, spores, fungi and viruses. This medicine is used as a solution for the preparation of the operating ophthalmic field (eyelids, eyelashes and cheeks) and for cleaning the eye and its surroundings in case of eye surgery.

2. What you need to know before you use Povidone iodine

Do not use Povidone iodine

- if you are allergic to povidone iodine or any of the other ingredients of this medicine (listed in section 6);
- if the patient is a new born infant up to one month of age;
- for administration by injection directly into the eye or in the areas around the eye (intraocular or periocular), the medicine is for external use;
- if you are using eye drops that contain mercury-based preservatives;
- if you are pregnant or breast-feeding (See section "Pregnancy and breast-feeding").

Warnings and precautions

This medicine will be given to you by your doctor or trained staff.

Talk to your doctor, pharmacist or nurse before using povidone iodine.

Use this medicine with caution:

- if you suffer any eye conditions that can promote the absorption of iodine into the blood;
- if you suffer from thyroid gland problems (due to the possibility of iodine absorption);

- if it is to be used on children less than 30 months of age. To maintain the conditions of sterility, the bag containing the bottle should only be opened shortly before use; the bottle is not sterile externally if the pouch that contains it is open or damaged. After use, the product must be thrown away even if used only partially.

Children

Do not use this medicine in infants up to one month of age.

Use this medicine with caution in children up to 30 months of age.

Other medicines and Povidone iodine

Tell your doctor, pharmacist or nurse if you are using, have recently used or might use any other medicines.

Avoid using Povidone iodine together with other antiseptic medicines or detergents.

Do not use Povidone iodine together with other medicines that contain mercury-based preservatives or together with sodium thiosulfate (iodine antidote).

Pregnancy and breastfeeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before using this medicine. Do not use Povidone iodine during pregnancy except in cases of real need and always under the direct supervision of your doctor.

If you are breastfeeding, the use of this medicine may cause unwanted effects in the infant. Therefore, contact your doctor who will have to evaluate whether to stop treatment with the medicine or stop breastfeeding.

Driving and using machines

Povidone iodine does not affect the ability to drive and use machines.

Povidone iodine contains phosphates

This medicine contains 1.5 mg phosphates in each ml. If you suffer from severe damage to the clear layer at the front of the eye (the cornea), phosphates may cause in very rare cases cloudy patches on the cornea due to calcium build-up during treatment.

3. How to use Povidone iodine

This medicine will be given to you by a doctor or other healthcare professional. Check with your doctor or pharmacist if you are not sure.

If you use more Povidone iodine than you should

This medicine will be given to you by a doctor or other healthcare professional, it is unlikely that you will be given an overdose. However, if you think that you have been given an excessive dose or have accidentally swallowed or inhaled the medicine, immediately notify your doctor or nurse who will take the appropriate precautions.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very rare (may affect up to 1 in 10,000 people):

- Mild allergic type reactions (hypersensitivity).
- Cloudy patches on the clear layer at the front of the eye (the cornea) due to calcium build-up during treatment in patients with severe damage to the cornea.

Not known (frequency cannot be estimated from the available data):

- Allergic type reactions, including difficulty breathing or swallowing, swelling of the face, lips, throat or tongue (anaphylactic shock and anaphylactoid reaction), skin rash with irritation and hives - red, raised, itchy bumps (urticaria).
- Effect on the thyroid due to regular and prolonged application of povidone iodine, causing the thyroid gland to not make enough thyroid hormones to meet the body's needs or in some cases resulting in an overactive thyroid gland (hypothyroidism), particularly in pre-term infants and neonates;
- Redness of the whites of the eyes (conjunctival redness);
- Eye irritation, superficial pinpoint inflammation of the surface of the eye (superficial punctate keratitis and epitheliopathy), dry eye syndrome (keratoconjunctivitis sicca);
- Residual yellow discoloration of the eyes and transient brown discoloration of the skin.
- Irritant effect on the membrane that lines the eyelid and the white of the eye causing redness, blisters and itching (contact dermatitis).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Povidone iodine

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton, sachet and bottle after "EXP".

The expiry date refers to the last day of that month.

Do not store above 25° C.

Throw away the bottle after first use, even if it contains residual medicine.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Povidone iodine contains

- The active substance is povidone iodine. 100 ml of solution contains 5 g of povidone iodine.
- The other ingredients are: glycerol, citric acid, polysorbate 20, dibasic sodium phosphate dodecahydrate, sodium chloride, potassium iodate, sodium hydroxide, purified water.

What Povidone iodine looks like and contents of the pack

Pack containing 1 bottle of 4.0 ml eye drops, solution.

The bottle is contained in a double sterile bag.

Marketing Authorization Holder

Alfa Intes Limited

Second Floor, 150 Fleet Street - London - United Kingdom

Distributor:

Penlan Pharmaceuticals Ltd, 5, The Heights, Weybridge, KT13 0NY, UK

Manufacturer

ALFA INTES Industria Terapeutica Splendore S.r.l.

Via F.lli Bandiera, 26 - 80026 Casoria (NA) - Italy

This leaflet was last revised in: November 2023.



Package leaflet: information for the physician

Povidone iodine

5% w/v eye drops solution

povidone, iodinated

The following information is intended for healthcare professionals only

Instructions for Use

Wash hands thoroughly before use.

Using the double package, transfer the product to the operating room with aseptic technique and use as described.

Saturate the sterile cotton wool with the liquid contained in the bottle and start preparing the lashes and eyelid margins.

Repeat for the eyelids, cheeks and forehead in a circular manner until the entire operating field is cleaned.

Repeat three times.

Place the blepharostat and irrigate the cornea, conjunctiva and eyelid fornix with product. Wait two minutes, then remove Povidone iodine from the ocular surface by

irrigating the cornea, conjunctiva, and fornixes with sterile sodium chloride 0.9% solution.

Do not touch the eye with the container nozzle.

After using the medicine, the single-use bottle should be thrown away even if partially used.

Overdose

In case of ocular overdose, wash abundantly with sterile sodium chloride 0.9% solution.

The accidental ingestion or inhalation of some disinfectants can have serious, sometimes fatal consequences.

In case of recent accidental ingestion of a large quantity of povidone iodine, gastric lavage should be used, otherwise supportive therapies should be used.

Interactions with other medicines and other forms of interaction

Avoid the simultaneous use of other antiseptics and detergents.

Povidone iodine should not be administered simultaneously with mercurial derivatives and sodium thiosulfate (the latter is in fact the antidote of iodine).

For more information, see the Summary of Product Characteristics.