

Package leaflet: Information for the user
Minims® Povidone 5% w/v eye drops, solution

Iodinated Povidone

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 or your pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Minims Povidone Iodine is and what it is used for
2. What you need to know before you use Minims Povidone Iodine
3. How to use Minims Povidone Iodine
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6. Contents of the pack and other information

1. WHAT MINIMS POVIDONE IODINE IS AND WHAT IT IS USED FOR

Minims Povidone Iodine is a solution that contains an antiseptic known as Iodinated Povidone in an eye drops solution.

It is used for cleaning the surface of your eye before eye surgery or eye injection.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE MINIMS POVIDONE IODINE

Do not use Minims Povidone Iodine

- If you are allergic to povidone iodine, or any product containing povidone iodine or any of the other ingredients of the medicine listed in section 6.
- In pre-term infants.
- For injecting into the eye and the eye surroundings.

Warnings and precautions

Talk to your doctor or pharmacist before taking Minims Povidone Iodine:

- If you have a thyroid disorder. Monitoring of thyroid function is should be considered, particularly in the elderly, during regular repeated use of this medicine.
- If you have dry eyes syndrome.

Special warnings

Minims Povidone Iodine 5% w/v eye drops, solution is strictly only for use to clean the eyes before surgery or eye injection and should not be used for any other purpose.

Precautions for use

After the medicine has been left in contact with the conjunctiva and the conjunctival sacs for 2 minutes, flush thoroughly with sterile 0.9 % NaCL solution.

Use with eye formulations containing mercury-based preservatives should be avoided.

Hypersensitivity (anaphylactoid reactions) to iodinated contrast agents or anaphylactic reaction to shellfish are not contraindications for Minims Povidone Iodine administration.

Other medicines and Minims Povidone Iodine

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

General

Use with other antiseptic agents should be avoided as these may affect the way Minims Povidone Iodine works.

Specific

Minims Povidone Iodine 5% w/v eye drops, should not be used with ocular formulations containing mercury-based preservatives due to the risk of formation of caustic compounds. Repeat use may interfere with thyroid function tests.

Pregnancy and breast-feeding

If you are pregnant or breastfeeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Minims Povidone Iodine is not meant for use outside the hospital or clinic and does not affect your ability to drive or use machines.

Minims Povidone Iodine contains disodium phosphate anhydrous.

This medicine contains 0.03 mg phosphates in each drop which is equivalent to 0.75 mg/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 MINIMS POVIDONE IODINE

Use in Adults

The drops are supplied in single-dose units that are meant to treat both eyes if both eyes are affected.

The recommended dose is two to three drops of the solution instilled onto the eye/eyes and leave for two minutes.

Use in Children and Adolescents

This product can be used in infants, children and adolescents. The recommended dose is the same as for adults.

Method and route of administration

Topical ocular route restricted to ocular surgery and eye injection. In the operating room/doctor's office (depending on the procedure) and after the anaesthetic has been applied to your eyes, the nurse or doctor will clean your eyes with Minims Povidone Iodine as follows:

1. The area around your eyes will be carefully cleaned with a sterile cotton swab.
2. The nurse / doctor will then twist off the cap of the Minims Povidone Iodine unit to open it.
3. Two to three drops of the solution will be gently dropped onto your eye/eyes.
4. You will be asked to close your eyes and roll your eyes around to spread the solution over the surface of the eyes.
5. The drops will be left on the eye / eyes for two minutes before rinsing. Your eyes will then be rinsed thoroughly with a sterile saline solution until the characteristic colour of the Iodinated Povidone disappears.

If you use more Minims Povidone Iodine than you should

If accidentally swallowed, contact a doctor as rapidly as possible.

If you forget to use Minims Povidone Iodine

Not applicable.

If you stop using Minims Povidone Iodine

Not applicable.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

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)

- In very rare cases, some patients with severe damage to the clear layer at the front of the eye (the cornea) have developed cloudy patches on the cornea due to calcium build-up during treatment.

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);
- Contact dermatitis. Irritant effect on the membrane that lines the eyelid and the white of the eye causing redness, blisters and itching;
- Regular and prolonged application of Minims Povidone Iodine may have an effect on the thyroid, 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, particularly in pre-term infants, neonates and the elderly;
- Conjunctival redness – redness of the whites of the eyes;
- 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.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

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

IE: HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971; Fax: +353 1 6762517, Website: www.hpra.ie; e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE MINIMS POVIDONE IODINE

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

For single use only. Discard immediately after first use.

Do not use this medicine after the expiry date which is stated on the overwrap of each unit and on the carton after the letters "EXP". The expiry date refers to the last day of that month.

Store between 2°C and 8°C.

Store in the original package to protect from light.

This medicine can be stored unrefrigerated below 25°C for up to one month. After this period the product should be discarded. When you take it out of the refrigerator, write the current date on the carton, as well as the date for a month later, so that you know when to discard the medicine.

Do not use Minims Povidone Iodine if you notice that the container is damaged.

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 Minims Povidone Iodine contains

- The active substance is Iodinated Povidone. Each single-dose container contains 20 mg of Iodinated Povidone in 0.4 ml of solution. One ml solution contains 50 mg Iodinated Povidone.
- The other ingredients are glycerol, nonoxinol 9, disodium phosphate anhydrous, citric acid monohydrate, sodium chloride, sodium hydroxide and purified water.

What Minims Povidone Iodine looks like and contents of the pack

This medicinal product is presented as eye drop solution in single-dose container marked with "PVI 5.0".

This solution is a deep brown-red coloured solution.

Each single-dose container is overwrapped in a plastic sachet. Each carton contains 20 single-dose containers.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holders:

UK: Bausch & Lomb U. K. Limited, 106 London Road, Kingston-Upon-Thames, Surrey KT2 6TN, United Kingdom

IE :

BAUSCH + LOMB IRELAND LIMITED
3013 Lake Drive
Citywest Business Campus
Dublin 24, D24PPT3
Ireland

Manufacturer:

Laboratoire Chauvin, Z.I.Ripotier Haut, 07200 Aubenas, France

This leaflet was last revised in June 2022.

The following information is intended for healthcare professionals only:Posology*Adults (including the elderly)*

Instill two to three drops of the solution onto the eye / eyes and leave for two minutes.

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 container to open it
- Do not touch the eye with the single-dose container nozzle
- Gently instill two to three 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

Contraindications

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

- Hypersensitivity to iodinated povidone, to iodine or to any of the medicinal product's excipients.
- In pre-term infants
- Minims Povidone Iodine 5% w/v eye drops, solution is contraindicated for intra-ocular or peri-ocular injection

Special precautions for storage

The product may be stored without refrigeration at not more than 25°C for up to one month. Where needed, the adhesive label provided in the carton may be completed and affixed in the area provided

on the carton by a pharmacist, indicating an expiry date of one month from the date of supply, date of removal from refrigerator, new expiry date and discard immediately after first use.