

Bausch & Lomb

Package leaflet: Information for the user

Minims® Pilocarpine Nitrate 2% w/v

Eye Drops, solution

Pilocarpine nitrate

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 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® Pilocarpine Nitrate eye drops are and what they are used for
2. What you need to know before you use Minims® Pilocarpine Nitrate
3. How to use Minims® Pilocarpine Nitrate
4. Possible side effects
5. How to store Minims® Pilocarpine Nitrate
6. Contents of the pack and other information

1. What Minims® Pilocarpine Nitrate eye drops are and what they are used for

Minims® Pilocarpine Nitrate contains a miotic agent. It is used to make the pupil of the eye smaller. Your doctor or eye specialist may use it to:

- reverse the effects of eye drops which cause the pupil to enlarge
- treat high pressure of liquid inside the eye (glaucoma) in emergency situation

This medicine is indicated for children, adults and the elderly.

2. What you need to know before you use Minims® Pilocarpine Nitrate

Do not use Minims® Pilocarpine Nitrate if:

- you are allergic to pilocarpine nitrate or any of the other ingredients of this medicine (listed in section 6).
- you have had an allergy to other miotic agents in the past
- you have some particular eye conditions where the constriction of the pupil should be avoided (e.g. inflammation of the iris, some forms of glaucoma)
- you wear soft contact lenses.

Warnings and precautions

Talk to your doctor or pharmacist before taking medication for:

- Heart disease (heart failure)
- Bronchial asthma
- Stomach ulcers
- High blood pressure
- Urinary tract obstruction
- Parkinson's disease
- Any other eye conditions

If the answer to any of these questions is yes, tell your doctor or eye specialist.

Other medicines and Minims® Pilocarpine Nitrate

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

- Creams or pills containing corticosteroids
- Medicines belonging to a family called anticholinergics
- Medicines used to treat allergic reactions (e.g. hayfever, hives) called antihistamines
- A pain killer called pethidine
- Medicines used to treat depression

- Any other medicine used to make the pupil of the eye smaller

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or eye specialist for advice before taking this medicine as he/ she may decide to use these drops or to prescribe you an alternative.

Contact lenses

Do not use these eye drops if you wear soft contact lenses. Your doctor will ask you to remove your contact lenses prior to the administration of the drops. There is no information on the effect of this product on contact lenses. Therefore, do not wear your contact lenses until the effects of the drops have completely worn off.

Driving and using machines

These eye drops may affect your ability to focus and/or see in the dark. As with all eye drops, your vision may be blurred after putting the drops in. Wait until your vision is clear before driving or using machines

3. How to use Minims® Pilocarpine Nitrate

The drops are for single use only and provided in single use Minims units, to treat both eyes if necessary. Once opened, use immediately. Discard any unused portion.

Dosage

Your doctor or eye specialist will decide the appropriate dosage of Minims® Pilocarpine depending on the reason for which it has been prescribed. He/she will give you more detailed instructions. Make sure you follow these instructions carefully.

Use in children and adolescents

Your child's doctor will start the treatment with Minims® Pilocarpine on the lowest available dose. Depending upon response and tolerance, the doctor may decide to increase the dose to the maximum recommended adult dosage of the 2% pilocarpine eye drop solution.

Method of administration

Make sure you follow these instructions carefully:

1. Wash your hands.
2. Use a mirror, this will help you to see what you are doing.
3. Carefully dry your eyes using a tissue. Twist and pull cap to separate from the Minims body (Diagram 1).
4. Pull your lower eyelid down gently, and then carefully place 1 or 2 drops inside your lower eyelid.
5. Close your eye and blink a few times to make sure your eye is covered by the liquid.
6. Close the eyelids. It is advisable to press gently on the inner corner of your eyelid for 1 minute. This will help stop the solution draining into your nose and throat. This is especially advisable in children, the elderly and population at risk.
7. Repeat steps 4, 5 and 6 for the other eye if necessary, then throw away the Minims unit, even if some solution remains.

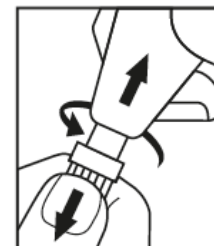


Diagram 1

If you use more Minims® Pilocarpine Nitrate than you should, an overdose is very unlikely to occur. If you suddenly feel unwell after receiving the drops, tell your doctor or eye specialist or contact your nearest emergency department immediately.

4. Possible side effects

- Like all medicines, this medicine can cause side effects, although not everybody gets them.
 - Reactions in and around the eyes can occur: sensations of burning, itching, stinging, blurring of vision, discomfort in the eyes and red eyes.
 - You may have difficulty to focus and/or adjust your eyes to the dark and experience bleeding in the main part of the eye.
 - You may experience changes to your eyes when you use the product for a long period.
 - Browache or headache may occasionally occur, especially in younger patients who have just started using this medicine.
 - Other reactions have been rarely reported: low blood pressure, abnormally slow heart beat, wheezing and shortness of breath, salivation, sweating, sickness, diarrhoea and watering of the eyes.
- If any of the side effects gets serious, please seek immediate medical attention. If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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:

United Kingdom

Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard

Ireland

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® Pilocarpine Nitrate

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

Do not use the eye drops 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.

Do not store above 25°C. Do not freeze. Store in the original package in order to protect from light.

The drops are for single use only and provided in single use Minims units, to treat both eyes if necessary. Once opened, use immediately.

Discard any unused portion.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Minims® Pilocarpine Nitrate contains

- The active ingredient is pilocarpine nitrate. Each Minims unit contains approximately 0.5 ml eye drops solution of pilocarpine nitrate 2% w/v (10 mg).
- The other ingredient is purified water.

This medicine does not contain a preservative as it is a sterile single use unit.

What Minims® Pilocarpine Nitrate looks like and contents of the pack

Minims® Pilocarpine Nitrate is a clear colorless solution. Each carton contains 20 units.

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