



BAUSCH + LOMB

Minims® Cyclopentolate Hydrochloride 0.5% w/v
Minims® Cyclopentolate Hydrochloride 1% w/v
 Eye Drops, solution
 Cyclopentolate Hydrochloride

Read all this leaflet carefully before you start using your medicine. It contains a summary of the information available on your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist. Remember this medicine is for you. Do not give it to someone else.

In this leaflet:

1. What Minims® Cyclopentolate Hydrochloride eye drops are and what they are used for
2. Before you use your eye drops
3. How to use your eye drops
4. Possible side effects
5. How to store your eye drops
6. Further information

1. What Minims® Cyclopentolate Hydrochloride eye drops are and what they are used for

Minims® Cyclopentolate Hydrochloride contains a mydriatic agent. It is used to enlarge the pupil of the eye and to paralyse the lens temporarily.

Your doctor or eye specialist may use it to examine your eye more closely. These eye drops are also used to treat some types of inflammation of the eye. This medicine is not indicated for babies under 28 days old.

However, your doctor or eye specialist can use it if he/she decides that it is necessary.

2. Before you use your eye drops**Do not use these drops**

- if you are allergic to the active substance (cyclopentolate hydrochloride) or any of the other ingredients (refer to the end of this leaflet).
- if you have high pressure of liquid inside the eye (closed angle glaucoma)
- in babies under 28 days old (unless your doctor decides that it is necessary)

Take special care

Ask yourself the following questions:

- Are your eyes red or inflamed?
- Is it to be used in very young children (under 3 months old)?
- Are you very ill?
- Are you elderly?

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

If you are pregnant, may be pregnant, or are breastfeeding

Tell your doctor or eye specialist, he/she may decide to use these drops or to prescribe you an alternative.

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

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 your eye drops

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

- The normal adult dose is 1 or 2 drops of solution in each eye, as required. The administration of the drops can be repeated every 6-8 hours, depending on the treatment.
- The normal child dose (over 3 months old) is 1 drop of Minims® Cyclopentolate Hydrochloride 0.5% w/v in each eye. Children should be observed for 45 minutes after the administration of the drops.

Method of administration

The doctor or eye specialist will normally put the drops in your eye for you, but if you are putting the eye drops in yourself, then 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, and twist off the cap from the Minims body of the unit.
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 3 minutes. 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.

If you use more Minims® Cyclopentolate Hydrochloride 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

The following side effects may occur:

- temporary irritation following the administration of the drops in your eyes.
 - increase of the pressure of liquid inside your eyes.
 - allergic reaction (including red eyes, watering of the eyes...) has been rarely reported.
- The following side effects may occur when using an unusual dosage, especially in children:
- temporary effect on your balance
 - temporary effects on your vision and sense of touch
 - confusion
 - fever
 - flushing of the face
 - hallucinations
 - skin rash
 - drowsiness
 - unusual behaviour
 - tachycardia

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.

5. How to store your eye drops

Keep out of the reach and sight 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 in special 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. Further information**What do your eye drops contain**

- The active ingredient is cyclopentolate hydrochloride. Each Minims unit contains approximately 0.5 ml eye drops solution of cyclopentolate hydrochloride 0.5% w/v (2.5 mg) or 1% w/v (5 mg).
- Not all strengths may be marketed.
- The other ingredients are hydrochloric acid (for pH adjustment) and purified water. This medicine does not contain a preservative as it is a sterile single use unit.

Contents of the pack

Each carton contains 20 units.

Marketing Authorisation Holder:

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Please contact the relevant competent authority.

Council of Arab Health Ministers

This is a medication

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medication.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

DATE OF PREPARATION: July 2015

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