

Minims® Cyclopentolate Hydrochloride 0.5% w/v
Minims® Cyclopentolate Hydrochloride 1% w/v

Eye Drops, solution

Cyclopentolate Hydrochloride

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

Do not use Minims® Cyclopentolate Hydrochloride eye drops:

- if you are allergic to the active substance (cyclopentolate hydrochloride) or any of the other ingredients (listed in section 6).
- in babies under 28 days old (unless your doctor decides that it is necessary).
- if you suffer from glaucoma (high pressure of liquid inside the eye) or if you are at risk of having it (i.e. your close family suffered from glaucoma, you are over 60, or you had an eye surgery). The doctor or eye specialist will check to make sure that this problem does not affect you.
- in children with brain damage, particularly if they may have seizures or fits.

Warnings and precautions

Ask yourself the following questions:

- Are your eyes red or inflamed?
- Do you have heart problems (in particular a fast heart rate or heart failure)?
- Do you have urinary tract disorders?
- Do you have long-term condition that causes muscle weakness (myasthenia gravis)?
- Do you have dry mucous membranes in your nose (rhinitis sicca)?
- Is it to be used in very young children (under 1 year old)?

- Do you suffer from ataxia (condition causing unsteadiness and coordination problems)?
- Do you suffer from, or are prone to increased eye pressure (especially in elderly patients)?
- Are you or is your child susceptible to belladonna alkaloids (for example, drugs such as atropine)?
- Do you have epilepsy?
- Do you have memory disorders such as dementia?
- Do you suffer from, or have a history of blockage in the intestines (gastrointestinal obstruction)?

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

Other medicines and Minims® Cyclopentolate Hydrochloride

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

The following medicines are known to interact with Minims® Cyclopentolate Hydrochloride:

- antihistamines
- butyrophenones, used to treat various psychiatric disorders such as schizophrenia, as well used to prevent nausea and vomiting
- medications for mental illness such as phenothiazines
- tricyclic and tetracyclic antidepressants
- amantadine, an antiviral drug used in the treatment of influenza A and Parkinson's disease
- quinidine and disopyramide, medicines for cardiac disorders
- oxybutynin, used to treat overactive bladder

Cyclopentolate may interfere with the eye pressure lowering actions of carbachol, pilocarpine, or ophthalmic cholinesterase inhibitors.

Pregnancy and breast-feeding

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 Minims® Cyclopentolate Hydrochloride eye drops

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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 – 12 years) is 1 drop of Minims® Cyclopentolate Hydrochloride 1 % w/v in each eye. For children above 12 years, the same dose as adults is recommended. 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 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.

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

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

You should contact your doctor immediately if you experience collapse, affecting breathing, heart rate and blood pressure, seizures, hallucinations, mental disturbances or any symptoms of a severe allergic reaction/anaphylactic shock. The symptoms of severe allergic reactions/ anaphylactic shock are difficulty breathing or swallowing, swelling of the face, lips, throat or tongue and severe skin rash.

The following side effects may occur:

Rare (may affect up to 1 in 1,000 people)

Immune system disorders:

- allergic reaction

Side effects with not known frequency (frequency cannot be estimated from available data)

Eye disorders:

- eye irritation
- accommodation disorder (an eye-focusing problem)

increased pressure inside the eye

- eye pain
- ocular hyperaemia (excessive blood in the vessels of the eye)
- vision blurred

conjunctivitis (commonly called “red eye”- inflammation of the outermost layer of the eye and inner surface of the eyelids)

Gastrointestinal disorders:

- abdominal distension (bloating of the stomach) in infants
- constipation
- dry mouth
- nausea
- vomiting
- necrotising colitis (intestinal tissue death) in preterm infants

Immune system disorders:

- hypersensitivity (both local and systemic hypersensitivity reactions) including anaphylactic reaction and anaphylactic shock

Nervous system disorders:

- gait disturbance (problems with walking normally)
- dizziness
- convulsions
- seizures (especially in children)
- cerebellar dysfunction (problems with walking, balance and coordination)
- somnolence(drowsiness)

Psychiatric disorders:

- hallucination
- abnormal behaviour
- psychotic disorders (including symptoms such as feeling restless, confusion and incoherent speech)

Cardiac disorders:

irregular heart rate (arrhythmia)

- collapse, affecting breathing, heart rate and blood pressure (cardiopulmonary failure)
- heart palpitations
- slow or faster heartbeat (tachycardia and bradycardia)

Vascular disorders:

- flushing

Skin and subcutaneous tissue disorders:

- dry skin
- rash

Renal and urinary disorders:

- urinary retention (difficulty passing urine)

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

UK: If you get any side effects, talk to your doctor or pharmacist. 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.

Malta: If you develop any side effects, including any that are not listed in this leaflet, please contact your doctor or pharmacist. You can also report side effects directly via the national reporting system at the website www.medicinesauthority.gov.mt/adrportal. By reporting side effects, you can help provide more information about the safety of this medicine.

5. How to store Minims® Cyclopentolate Hydrochloride eye drops

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 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.

Do not throw away any medicines 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® Cyclopentolate Hydrochloride contains

- The active substance 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).
- 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 Holders:

UK: Bausch & Lomb UK LTD,
106 London Road,
Kingston-Upon-Thames,
Surrey, KT2 6TN, United Kingdom

MT:

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

Manufacturer:

Laboratoire Chauvin - Z.I.Ripotier - 07200 Aubenas – France

Marketing Authorisation Numbers:

Minims® Cyclopentolate Hydrochloride 0.5% w/v:
PL 03468/0070 (UK)

Minims® Cyclopentolate Hydrochloride 1% w/v:
PL 03468/0071 (UK); MA 1467/00302 (MT)

DATE OF PREPARATION: February 2024