

# **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.

## **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 your eye drops
3. How to use your eye drops
4. Possible side effects
5. How to store your 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 is a mydriatic and cycloplegic drug. 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 and/or prepare the eye for an operation.

These eye drops are also used to treat some types of inflammation of the eye.

This medicine is indicated in adults and children over the age of 1 years

## **2. What you need to know before you use your 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 of this medicine (listed in section 6).
- if you have high pressure of liquid inside the eye (closed angle glaucoma).
- in premature infants and neonates
- if you have paralysis of the bowel.

### **Warnings and precautions**

Talk to your doctor or pharmacist before using Minims® Cyclopentolate Hydrochloride eye drops, especially when:

- you are elderly
- you use this drug in inflamed or red eye
- you are elderly and have cognitive disorders
- you have ataxia (reduced voluntary coordination of muscle movements)
- you have rhinitis sicca

- if you have gastrointestinal tract and/or urinary tract disorders
- if you have long term condition that causes muscle weakness (myasthenia gravis)
- you have cardiovascular disease (conditions affecting the heart or blood vessels)
- you have glaucoma or increased intraocular pressure
- 
- you have epilepsy
- you have prostate disorders,
- it is to be used in children
- you have or your child has brain damage
- you are or your child is particularly susceptible to severe central nervous system disorders
- you are or your child is susceptible to belladonna alkaloids.

Because of risk of angle-closure glaucoma (having an increased pressure in the eye), especially if you are elderly, or at risk of high pressure in the eye, the doctor or eye specialist will check to make sure that this problem does not affect you.

After application, recovery of accommodation and normal vision usually occurs within 24 hours.

### **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
- 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,
- metoclopramide, a medicine used to prevent nausea and vomiting.

Cyclopentolate may interfere with the ocular anti-hypertensive action of carbachol, pilocarpine, or ophthalmic cholinesterase inhibitors.

Physostigmine or pilocarpine terminate the pupil dilatating effect (mydriatic effect) of Minims® Cyclopentolate Hydrochloride eye drops.

### **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 pharmacist for advice before taking this medicine. Cyclopentolate should not be used during pregnancy and 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**

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.

#### **The recommended dose in adults (including elderly):**

In order to examine your eyes closely, the doctor or eye specialist may put a drop of cyclopentolate into your eye.

If cyclopentolate has been prescribed to you because your eye is inflamed (red and painful) you will usually be asked to put 1-2 drops into your eye every 6 to 8 hours, however, this may vary. Your doctor or pharmacist will give you more detailed instructions, which you should follow carefully.

#### **Use in children and adolescents**

This medicine is indicated for use in children over the age of 1 years, it is not recommended for use in children younger than 1 year of age.

The dose for children depends on their size, age and the effect of the first drop. Usually, 1-2 drops are put into the eye. The doctor or eye specialist will decide how much to use. Observe children closely for at least 30 minutes after cyclopentolate eyedrop use.

#### **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 hands thoroughly, peel the overwrap apart and take out the Minims unit.
2. Twist off the cap.
3. Look upwards and gently pull down the lower eyelid.
4. Hold the Minims unit just above your eye and gently squeeze until a drop of liquid falls into the gap between your eyeball and lower eyelid. Make sure the dropper does not touch any part of your eye.
5. Release the lower eyelid and then press gently on the inner corner of your eye for a minute or so. This will help to stop the solution draining away into your nose and throat. This is especially advisable in children.
6. Throw away the rest of the Minims unit when you have finished, even if there is some solution left.

#### **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.

#### **If you forget to use Minims® Cyclopentolate Hydrochloride**

Do not take a double dose to make up for a forgotten dose.

#### **If you stop using Minims® Cyclopentolate Hydrochloride**

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.

Tell your doctor if you have any of the following side effects, they become worse or you notice any effects not listed.

You should contact your doctor immediately if you experience 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.

**Common (may affect up to 1 in 10 people)**

- eye irritation, stinging following the instillation of this drug into your eye
- fever
- temporary effect on your balance, vision and sense of touch (e.g. hallucinations), confusion
- flushing of the face
- gastrointestinal hypomotility (decreased contractile forces of gastrointestinal tract or slower transit of food) leading to constipation

**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:

- accommodation disorder (an eye-focusing problem)
- angle closure glaucoma (high pressure inside the eye)
- eye pain
- swelling of the eye
- ocular hyperaemia (excessive blood in the vessels of the eye)
- vision blurred
- visual impairment

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

Infections and infestations:

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

#### Investigations:

- increased intraocular pressure

#### Nervous system disorders:

- ataxia (problems with coordination, balance and speech)
- balance disorder
- central nervous system disturbances
- dizziness
- dysarthria (difficulties in speaking)
- incoherent (in children) - speaking in nonsensible ways
- psychomotor hyperactivity
- drowsiness
- seizures (especially in children)
- cerebellar dysfunction (balance problems and gait disorders)
- somnolence

#### Psychiatric disorders:

- agitation
- abnormal behaviour (especially in children)
- disorientation
- psychotic disorder
- restlessness (anxiety)

#### 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)

#### Skin and subcutaneous tissue disorders:

- dry skin
- erythema (redness of the skin)
- skin rash

#### Renal and urinary disorders:

- urinary retention (difficulty passing urine)

#### General disorders and administration site conditions:

- mucosal dryness.

#### **Reporting of side effects**

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:

HPRA Pharmacovigilance  
Website: [www.hpra.ie](http://www.hpra.ie)

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

## **5. How to store your eye drops**

Keep 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.

Minims Cyclopentolate should be stored below 25°C and protected from strong light. Do not allow to freeze.

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 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 your eye drops contain**

- The active substance is cyclopentolate hydrochloride. Each Minims unit contains approximately 0.5 ml eye drops solution of cyclopentolate hydrochloride 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.

### **What your eye drops look like and contents of the pack**

The eye drops are a clear, colorless solution. Each carton contains 20 units.

### **Marketing Authorisation Holder:**

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

### **Manufacturer:**

Laboratoire Chauvin  
Zone Industrielle de Ripotier  
50 Avenue Jean Monnet  
07200 Aubenas  
France

**Marketing Authorisation Numbers:** PA23259/011/001

**DATE OF PREPARATION:** October 2023