Minims® Cyclopentolate

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Minims Cyclopentolate?

Minims Cyclopentolate contains the active ingredient cyclopentolate hydrochloride. Minims Cyclopentolate is used to temporarily dilate (enlarge) the pupil of the eye and to stop the movement of the muscles that change the shape of the lens. It is usually used at the beginning of an eye examination so that your doctor can examine your eye(s).

For more information, see Section <u>1. Why am I using Minims Cyclopentolate?</u> in the full CMI.

2. What should I know before I use Minims Cyclopentolate?

Do not use if you have ever had an allergic reaction to cyclopentolate or any of the ingredients listed at the end of the CMI. Do not use if you have narrow angle glaucoma, shallow anterior chamber, Down's syndrome, heart or blood vessel conditions, are aged over 65 years, are at risk of having high pressure in your eye, your child is a premature baby, infant less than 3 months old, small child, has brain damage or brain syndromes. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section 2. What should I know before I use Minims Cyclopentolate? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Minims Cyclopentolate and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Minims Cyclopentolate?

Your doctor will normally instil the drops into your eyes for you. The usual dose is one or two drops instilled into the eye.

If your doctor instructs you to instil the drops, more instructions can be found in Section <u>4. How do I use Minims Cyclopentolate?</u> in the full CMI.

5. What should I know while using Minims Cyclopentolate?

Things you should do	 If you have any irritation, pain, swelling, excessive tear production or light-sensitivity while using the eye drops, flush the treated eye(s) with lots of water (room temperature) for at least 15 minutes. Stop using the eye drops and contact your doctor. Your eyes may be sensitive to light while using this medicine. It is recommended that you protect your eyes from light e.g. by wearing sunglasses. 	
Things you should not do	 Do not use this medicine to treat any other complaints unless your doctor tells you to. Do not give this medicine to anyone else, even if you think they have the same condition as you. 	
Driving or using machines	 Be careful before you drive or use any machines or tools until you know how Minims Cyclopentolate affects you. It may cause blurred vision for a short time when it is instilled into the eye. Allow enough time to regain clear vision before driving or using machines. 	
Looking after your medicine	• Keep the unopened eye drops in a refrigerator (2-8°C) where children cannot reach them. Do not freeze the eye drops or expose them to strong light.	

For more information, see Section 5. What should I know while using Minims Cyclopentolate? in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If they do occur, they are usually minor and temporary. Do not be alarmed by this list. You may not experience any of them. Less serious side effects include: blurred vision and/or problems seeing clearly, local irritation, stinging or the feeling of having something in the eye, burning or painful sensation, red, watery and itchy eyes and sensitivity to light. Serious side effects include: allergic reaction, angle closure glaucoma and effects to the body as a whole.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Minims® Cyclopentolate

Active ingredient: Cyclopentolate hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using Minims Cyclopentolate. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Minims Cyclopentolate.

Where to find information in this leaflet:

- 1. Why am I using Minims Cyclopentolate?
- 2. What should I know before I use Minims Cyclopentolate?
- 3. What if I am taking other medicines?
- 4. How do I use Minims Cyclopentolate?
- 5. What should I know while using Minims Cyclopentolate?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using Minims Cyclopentolate?

Minims Cyclopentolate contains the active ingredient cyclopentolate hydrochloride. Minims Cyclopentolate belongs to a class of medicines called antimuscarinic agents.

Minims Cyclopentolate is used to temporarily dilate (enlarge) the pupil of the eye and to stop the movement of the muscles that change the shape of the lens. It is usually used at the beginning of an eye examination so that your doctor can examine your eye(s).

2. What should I know before I use Minims Cyclopentolate?

Warnings

Do not use Minims Cyclopentolate if:

- You are allergic to cyclopentolate, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- You have or suspect you have narrow angle glaucoma (high pressure in the eye). Cyclopentolate can increase the pressure in the eye.
- You have a shallow anterior chamber (when the part of the eye between the cornea and the iris is narrow)
- You are aged over 65 years.
- You are at risk of having high pressure in your eye
- Your child is a premature baby, infant less than 3 months old, small child, has brain damage or brain syndromes.
- You have Down's syndrome.
- You have cardiovascular disorders (heart or blood vessel conditions).

Check with your doctor if:

- You have had an allergy to any other medicines, foods, preservatives or dyes.
- You have any other medical conditions, especially:
 - glaucoma (high pressure in the eye)
 - epilepsy (condition where you have repeated fits or convulsions)
 - o prostate disorders
 - \circ ataxia (poor balance or coordination)
 - dementia (condition where you have memory loss)
 - o rhinitis sicca (dry nose)
 - gut disorders where the gut is partly blocked or narrow, or where the large intestine is inflamed
 - myasthenia gravis (a condition in which the muscles become weak and tire easily)
 - $\circ \quad \text{obstructive urinary tract disorders}$
- You have hyperaemia (high blood flow e.g., red eyes)
- Your child is easily affected by belladonna alkaloids (some medicines used to treat lung disease, nausea and vomiting)
- You take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6. Are there any side effects</u>?

This medicine has been developed for use in the eye only. It should not be swallowed or injected.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Use in children

Minims Cyclopentolate should be used with caution in children.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Minims Cyclopentolate may interfere with each other. These medicines may be affected by Minims Cyclopentolate or may affect how well it works. These include:

- Medicines to treat glaucoma
- Antihistamines
- Some medicines used to treat depression
- Some medicines used to treat mental illness

- Some medicines used to treat Parkinson's disease
- Some medicines used to treat irregular heartbeats
- Some medicines used to treat nausea and vomiting.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Minims Cyclopentolate.

4. How do I use Minims Cyclopentolate?

Your doctor will normally instil the drops into your eyes for you. If your doctor instructs you to instil the drops, please follow the directions below.

How much to use

- Use Minims Cyclopentolate only when prescribed by your doctor. Your doctor will tell you how often to use the eye drops and how many drops to use each time.
- The usual dose is one or two drops instilled into the eye(s).

How to use Minims Cyclopentolate

If you are wearing contact lenses, remove them before putting the drops in your eye.

You may find it easier to put drops in your eye while you are sitting or lying down.

If you are instilling your own drops, then follow these steps to use the eye drops:

- 1. Wash your hands well with soap and water.
- 2. Shake the container.
- 3. Break the seal.
- 4. Hold the container upside down in one hand between your thumb and forefinger.
- 5. Using your other hand, gently pull down your lower eyelid to form a pouch or pocket.
- 6. Tilt your head back and look up.
- Put the tip of the container close to your lower eyelid. Do not let it touch your eye.
- 8. Release the required number of drops into the pouch or pocket formed between your eye and eyelid by gently squeezing the container.
- 9. Close your eye. Do not blink or rub your eye.
- 10. While your eye is closed, place your index finger against the inside corner of your eye and press against your nose for about two minutes. This is very important when administering to children. This will help to stop the medicine from draining through the tear duct to the nose and throat, from where it can be absorbed into other parts of your body.
- 11. Repeat steps 4-10 for the other eye if needed.
- 12. Throw away any eye drops left in the container.
- 13. Wait at least 15 minutes before replacing your contact lenses.

If you use too much Minims Cyclopentolate

Overdose or accidental swallowing of Minims Cyclopentolate may possibly cause side effects due to absorption, particularly in infants or young children. If you think that you or anyone else may have swallowed Minims Cyclopentolate or used too much Minims Cyclopentolate, you should immediately:

- phone the Poisons Information Centre (in New Zealand phone 0800 764 766), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Minims Cyclopentolate?

Things you should do

- If you experience any irritation, pain, swelling, excessive tear production or light-sensitivity while using the eye drops, flush the treated eye(s) with lots of water (room temperature) for at least 15 minutes. Stop using the eye drops and contact your doctor if these symptoms persist.
- Your eyes may be sensitive to light while using this medicine. It is recommended that you protect your eyes from light e.g. by wearing sunglasses.

Things you should not do

- Do not use this medicine to treat any other complaints unless your doctor tells you to.
- Do not give this medicine to anyone else, even if you think they have the same condition as you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Minims Cyclopentolate affects you.

Minims Cyclopentolate may cause blurred vision for a short time when it is instilled into the eye. Allow enough time to regain clear vision before driving or using machines.

Looking after your medicine

Keep the unopened eye drops in a refrigerator (2-8°C) where children cannot reach them. Do not freeze the eye drops or expose them to strong light.

When to discard your medicine

Discard each single dose unit and any remaining solution in it immediately after use. Do not save unused contents.

Getting rid of any unwanted medicine

If your doctor tells you to stop using the eye drops or it is out of date or damaged, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date or if the packaging is torn or shows signs of tampering.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
 Eyes: blurred vision and/or problems seeing clearly local irritation or stinging or the feeling of having something in the eye burning or painful sensation red, watery and itchy eyes sensitivity to light 	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Ser	Serious side effects What to do				
Symptoms of an allergic reaction,		Call your doctor			
-	h as:	straight away,			
-	shortness of breath wheezing or difficulty breathing swelling of the face, lips, tongue or other parts of the body rash, itching or hives on the skin. mptoms of angle closure ucoma, such as: Severe headache Severe eye pain Nausea or vomiting Blurred vision Halos or coloured rings around lights	or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.			
•	Eye redness.				
-	nptoms of toxicity or effects to body as a whole, such as:				
•	mental or behaviour changes, such as restlessness, hallucinations, hyperactivity, confusion or agitation nervous system effects, such as poor balance or muscle control, fits or seizures, drowsiness, speech difficulty, dizziness or involuntary shaking				
•	dry mouth skin effects, such as dry skin, skin rash, flushing or skin redness				
• • •	temperature changes or fever effects on the gut, such as swelling, infection, feeding problems in infants, constipation, slow gut movement, nausea or vomiting difficulty in passing urine heart rate changes sudden loss of breathing or heart function				

Some side effects (for example, an increase in the pressure of the eye) can only be found when your doctor or optometrist does tests from time to time.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects online (in New Zealand, go to https://nzphvc.otago.ac.nz/reporting). By

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

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Minims Cyclopentolate contains

Active ingredient	cyclopentolate hydrochloride	
(main ingredient)	(0.5% w/v or 1% w/v)	
Other ingredients (inactive ingredients)	 Purified water Hydrochloric acid	

Do not take this medicine if you are allergic to any of these ingredients.

The eye drops do not contain any preservatives.

What Minims Cyclopentolate looks like

Minims Cyclopentolate is available in two strengths:

- Minims Cyclopentolate Hydrochloride 0.5% eye drops
- Minims Cyclopentolate Hydrochloride 1% eye drops

Minims Cyclopentolate comes in single dose units (tubes) containing 0.5mL of a clear, colourless solution. Each tube is wrapped in a polyester/paper blister. The blisters are packed in cartons of 20 units.

Who distributes Minims Cyclopentolate

In New Zealand, Minims Cyclopentolate is supplied by: Bausch & Lomb (NZ) Ltd c/- Bell Gully Auckland Vero Centre 48 Shortland Street Auckland 1140 New Zealand

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Toll free number: 0508375394