

Alcon Laboratories SA (Pty) Ltd	Date: 07 Feb 2023
Cyclogyl® 1 % Eye Drops Solution	

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PATIENT INFORMATION LEAFLET

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SCHEDULING STATUS:

S3

CYCLOGYL® 1 % Eye Drops
Cyclopentolate hydrochloride 10 mg / ml solution
Sugar free

Read all of this leaflet carefully before you start using CYCLOGYL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- CYCLOGYL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What CYCLOGYL is and what it is used for
2. What you need to know before you use CYCLOGYL
3. How to use CYCLOGYL
4. Possible side effects
5. How to store CYCLOGYL
6. Contents of the pack and other information

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1. What CYCLOGYL is and what it is used for

CYCLOGYL is an eye drop solution used to widen the pupil of the eye to enable examination of the inside of the eye.

2. What you need to know before you use CYCLOGYL

- Do not use CYCLOGYL
- if you are hypersensitive (allergic) to cyclopentolate or any of the other ingredients of CYCLOGYL (listed in section 6).
- if you have or think you might have angle-closure glaucoma

Warnings and precautions

Special care should be taken with CYCLOGYL:

CYCLOGYL is only for use as an eye drop.

Use extreme caution if CYCLOGYL 1 % is to be used in small infants because of the risk of serious adverse reactions.

Tell your doctor or healthcare professional

- if you have previously had a severe reaction to atropine
- if you have a fever or are exposed to hot climates, especially in children.

CYCLOGYL may cause:

- an increase in the pressure in your eye. You should have your

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eye pressure checked before initiation of therapy, especially if

you are elderly

- changes in behaviour, especially with children and the elderly,

but reactions may occur at any age. Consult your doctor for

advice.

- sensitivity to light; wear sunglasses to protect your eyes in bright

illumination.

Take special care with CYCLOGYL:

- Serious side effects may occur if CYCLOGYL is administered to infants and young children, or children with Down syndrome, spastic paralysis, brain damage, known epilepsy or children with fair skin and blue eyes; consult your doctor for advice; observe infants closely for at least 30 minutes after instilling the drops.
- Withhold feeding from infants for 4 hours after dosing as

CYCLOGYL may cause them to react to their feed.

- Do not get CYCLOGYL in your child's mouth or cheeks; wash your hands and your child's hands or cheeks immediately after administration

Other medicines and CYCLOGYL

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor if you are taking antihistamines or medicines for Parkinson's disease, depression or anxiety as they may increase the effect of CYCLOGYL.

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Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

The safety of CYCLOGYL during pregnancy and breast-feeding has not been established. It is not known whether CYCLOGYL is distributed into breast milk.

Driving and using machines

CYCLOGYL may cause drowsiness, blurred vision and sensitivity to light. Do not drive or use machines until your vision has cleared. Wear sunglasses to protect your eyes.

CYCLOGYL contains benzalkonium

CYCLOGYL contains benzalkonium chloride which may cause eye irritation and is also known to discolour soft contact lenses.

Remove your contact lenses before using CYCLOGYL and wait at least 15 minutes before putting them back.

3. How to use CYCLOGYL

ADULTS: the usual dose is one drop in the eye to be examined followed by a second drop in 5 minutes.

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CHILDREN: one drop is instilled in the eye at the time of examination. If necessary a second drop may be instilled after 10 minutes. After CYCLOGYL is instilled close your eye and press gently with a finger into the corner of your eye, next to the nose and hold for 1 minute.

This helps to stop CYCLOGYL getting into the rest of the body and causing side effects.

If you use more CYCLOGYL than you should

Since a healthcare professional will administer CYCLOGYL, they will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you stop taking CYCLOGYL

Your pupils will return to normal size after a day.

4. Possible side effects

CYCLOGYL can have side effects.

Not all side effects reported for CYCLOGYL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using please consult your health care provider for advice.

Stinging may occur briefly at the time of instillation and eye inflammation may develop.

The following side effects have been seen with CYCLOGYL. Frequency cannot be estimated from the available data:

Effects in the eye:

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sensitivity to light, increase in pupil size prolonged, eye irritation, blurred vision, eye pain.

General side effects:

allergy, hallucination, state of confusion, disorientation, agitation, restlessness, incoherence, loss of recent memories, dizziness, headache, drowsiness, vomiting, nausea, dry mouth, skin redness, difficulty in walking, fever, fatigue.

Reporting of side effects

If you get side effects, talk to your doctor or, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of CYCLOGYL.

5. How to store CYCLOGYL

Store all medicines out of reach of children.

Keep in a cool place below 25 °C.

6. Contents of the pack and other information

What CYCLOGYL contains

The active substance is cyclopentolate hydrochloride

The other ingredients are boric acid, potassium chloride, sodium edetate, purified water.

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The preservative is benzalkonium chloride 0,01 %

What CYCLOGYL looks like and contents of the pack

A clear, colourless liquid.

Natural Drop-Tainer™ bottle containing 15 ml, fitted with a natural dispensing tip as plug and red linerless screw cap

Holder of certificate of registration

Alcon Laboratories SA (Pty) Ltd

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Jukskei View, Waterfall City,

Johannesburg, 2090

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