PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

MINIMS® CYCLOPENTOLATE HYDROCHLORIDE 1,0 %

Eye drops, solution in single-dose container

Read all of this leaflet carefully before you start using MINIMS® Cyclopentolate

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

1. What MINIMS® Cyclopentolate is and what it is used for

A 15.4 Ophthalmic preparation: Other

MINIMS® Cyclopentolate eye drops is used to dilate (enlarge) the pupil of the eye and to temporarily paralyse the lens so that your doctor can examine your eye(s). It is usually used at the beginning of an eye examination.

2. What you need to know before you use MINIMS® Cyclopentolate

Do not use MINIMS® Cyclopentolate:

- if you are hypersensitive (allergic) to cyclopentolate or any of the other ingredients of MINIMS® Cyclopentolate eye drops (listed in section 6).
- if you have or suspect you have angle closure glaucoma (high pressure in the eye). Cyclopentolate can increase the pressure in the eye.
- In neonates or infants less than 3 months old

Tell your doctor before being given MINIMS® Cyclopentolate:

- if you have had an allergy to any other medicines, foods, preservatives or dyes
- if you have or have had glaucoma (high pressure in the eye)
- if you have Down's syndrome
- if your child has brain damage or spastic paralysis

Warnings and precautions

MINIMS® Cyclopentolate eye drops are for use in your eyes only. The solution should not be injected.

Your eyes may become sensitive to light while using MINIMS® Cyclopentolate eye drops, protect your eyes, e.g. by wearing sunglasses.

Cyclopentolate may cause side effects, especially in younger patients and other patients at special risk, such as debilitated or aged patients. You can avoid absorption of cyclopentolate into the systemic circulation by compressing the tear duct in the corner of your eye for a minute during and following the instillation of the drops. This is especially advisable in children.

Children

Do not use MINIMS® Cyclopentolate in premature and small infants, and use with great caution in young children and children with spastic paralysis or brain damage, because of the increased risk of side effects.

The doctor should monitor children closely for 45 minutes after instillation of MINIMS® Cyclopentolate eye drops.

Parents should avoid contact of the solution with the child's mouth, and wash your hands and the child's hands after administering the drops.

Use in the elderly

MINIMS® Cyclopentolate should be used with caution in elderly patients, who may have increased pressure in their eye, or be more susceptible to the side effects of cyclopentolate.

Other medicines and MINIMS® Cyclopentolate

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

Some medicines and MINIMS® Cyclopentolate may interfere with each other. These include:

- medicines used to treat glaucoma, such as carbachol or pilocarpine,
- similar medicines (such as atropine, hyoscine and tropicamide) that are used to treat conditions that affect the body rather than just the eye.

Pregnancy, breastfeeding and fertility

The safety for use in pregnancy or breastfeeding has not been established.

No studies have been performed to determine whether MINIMS® Cyclopentolate may have an effect on 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 using this medicine.

Driving and using machines

MINIMS® Cyclopentolate eye drops may cause transient blurring of vision on instillation. You should not to drive or operate hazardous machinery until your vision is clear.

3. How to use MINIMS® Cyclopentolate

Do not share medicines prescribed for you with any other person. Always use MINIMS® Cyclopentolate eye drops exactly as your doctor has told you. Check with our doctor if you are

not sure.

Normally, you will not be expected to give yourself MINIMS® Cyclopentolate eye drops. It will be instilled into your eye(s) by a person who is qualified to do so. Your doctor will determine the strength of the solution and number of drops required.

The usual dose is one drop instilled into the eye(s).

If you use more MINIMS® Cyclopentolate than you should

Overdose or accidental swallowing of the solution may possibly cause side effects due to absorption, especially in infants or young children.

If you think that someone may have swallowed any or all of the contents of the container of MINIMS® Cyclopentolate, or in the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

4. Possible side effects

MINIMS® Cyclopentolate can have side effects.

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

If any of the following happens, stop using MINIMS® Cyclopentolate eye drops and tell your doctor immediately or go to the casualty department at your nearest hospital:

- 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, or
- fainting

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to MINIMS® Cyclopentolate eye drops. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- behavioural changes (these are more common in children),
- seizures or fits (especially in children),
- sleepiness or drowsiness,
- incoherent speech,
- restlessness,
- hallucinations,
- hyperactivity
- disorientation

These are all serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following in your eyes and they become bothersome:

- blurred vision or problems seeing clearly,

- local irritation, stinging or feeling of having something in the eye,
- burning sensation,
- red eyes,
- itching,
- tearing, or
- sensitivity to light

Other side effects have also been reported, tell your doctor if you notice any of the following:

- flushing,
- dry skin or mouth,
- temperature changes,
- if your bladder does not empty completely,
- feeling dizzy,
- incoordination,
- poor balance,
- shaking,
- if your heart beats faster than normal,
- constipation, vomiting, diarrhoea, or
- feeding intolerance in infants.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to Holder of the Certificate of registration using the following e-mail address: PV-SouthAfrica@bauschhealth.com, or directly to SAHPRA using an ADR reporting form or the e-reporting portal available on SAHPRA'S website: https://www.sahpra.org.za/health-products-vigilance/

By reporting side effects, you can help provide more information on the safety of MINIMS® Cyclopentolate.

5. How to store MINIMS® Cyclopentolate

Store all medicines out of reach of children.

- Store between 2 °C – 8 °C in a refrigerator
- Protect from light
- Do not freeze
- Keep the units in the outer carton
- Do not use after the expiry date stated on the carton or unit
- Discard each MINIMS® unit after single use

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What MINIMS® Cyclopentolate contains

- The active substance is cyclopentolate. Each dispensing unit of 0,5 ml contains 5,0 mg cyclopentolate (1,0 % *m/v*)
- The other ingredients are purified water and hydrochloric acid (for pH adjustment)

What MINIMS® Cyclopentolate looks like and contents of the pack

MINIMS® Cyclopentolate is an eye drops solution in a single-dose container.

The eye drops are a clear, colourless solution reasonably free from visible particulate matter.

MINIMS® Cyclopentolate eye drops are provided in a sealed polypropylene tube (unit), fitted with a polypropylene twist and pull-off cap. Each unit contains approximately 0,5 ml of solution.

Each unit is individually overwrapped in a polypropylene/paper sachet. The sachets are packed in cartons of 20 units.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

The Professional Information is available on the company website, www.bausch.co.za, or may be requested telephonically: +27 10 025 2100.