PROFESSIONAL INFORMATION

SCHEDULING STATUS

S3

1 NAME OF THE MEDICINE

MINIMS® CYCLOPENTOLATE HYDROCHLORIDE 1,0 %

Eye drops, solution in single-dose container

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sterile preservative-free solution containing 5,0 mg cyclopentolate hydrochloride per dispensing unit of 0,5 ml (1,0 % *m/v*) as the active ingredient.

For full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution in single-dose container

A clear, colourless solution reasonably free from visible particulate matter.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Mydriasis and cycloplegia: iridocyclitis; applanation tonometry.

The maximum effect is produced in 30 - 60 minutes after instillation; recovery of accommodation occurs within 24 hours, but may be hastened if one or two drops of a 2 % solution of pilocarpine nitrate are instilled.

4.2 Posology and method of administration

Adults and Children: To be used as directed by the ophthalmologist.

For refraction:

Adults: one drop of solution repeated after 5 minutes is usually sufficient, but deeply pigmented eyes may require dose adjustment.

Children one year and older: one drop of solution. Children should be observed for 45 minutes after instillation.

For iridocyclitis:

Adults, only: In iritis or iridocyclitis one drop of solution is instilled every six to eight hours.

4.3 Contraindications

- Hypersensitivity to cyclopentolate hydrochloride or any other ingredients (see Section 6.1).
- Cyclopentolate hydrochloride should not be administered to patients with narrow-angle glaucoma, or to those with a narrow angle between the iris and the cornea, since its use may increase intra-ocular pressure.
- Cyclopentolate hydrochloride should not be used in neonates.

- Do not use in sensitive patients, especially infants, premature births, small children, adults over 65 years old and patients with Down's syndrome, as well as in children with brain damage (see section 4.4).
- Children below 1 year of age.
- Do not use in children with organic brain syndromes, including congenital or neuro-developmental abnormalities, particularly those predisposing to epileptic seizures.

4.4 Special warnings and precautions for use

MINIMS® Cyclopentolate eye drops are for topical ophthalmic use only. The solution should not be injected.

Complete recovery of accommodation usually occurs within 24 hours, however complete recovery may require several days in some individuals.

Eyes may become sensitive to light while using MINIMS® Cyclopentolate eye drops. Patients should be advised to protect their eyes, e.g. by wearing sunglasses.

Cyclopentolate may cause central nervous system (CNS) disturbances when administered topically to the eye. This is especially true in younger age groups and other patients at special risk, such as debilitated or aged patients, but may occur at any age.

Caution should be observed when considering the use of this medication in those predisposed to angle closure glaucoma. To avoid inducing angle closure glaucoma, an estimation of the depth of the anterior chamber should be made.

Resistance to cycloplegia can occur in young children in patients with dark irides (see Section 4.2).

Caution is advised in hyperaemia as increased systemic absorption may occur.

Systemic absorption of cyclopentolate may be reduced by compressing the lacrimal sac at the medial canthus for a minute during and following the instillation of the drops. This blocks the passage of the drops via the naso-lacrimal duct to the wide absorptive area of the nasal and pharyngeal mucosa. It is especially advisable in children.

Paediatric population

Extreme caution is advised for use in individuals susceptible to belladonna alkaloids because of the increased risk of systemic toxicity. Atropine-like effects have been reported as side effects.

MINIMS® Cyclopentolate eye drops should not be used in new-borns or infants under the age of 1 year due to the increased risk of systemic toxicity (see section 4.3). MINIMS® Cyclopentolate eye drops should be used with caution in children over 1 year of age and with extreme caution in those who are particularly susceptible to severe central nervous system disorders (e.g. epilepsy, brain injury, Down's syndrome) as there is an increased risk of toxicity in the central nervous system, cardiopulmonary, and gastrointestinal, systems due to systemic uptake of cyclopentolate (see section 4.8).

Use of cyclopentolate has been associated with psychotic reactions, and behavioural disturbances in paediatric patients. Increased susceptibility to cyclopentolate has been reported in infants, young children and in children with brain damage. These disturbances include ataxia, incoherent speech, restlessness, hallucinations, hyperactivity, seizures, disorientation as to time and place and failure to recognise people.

Feeding intolerance may follow ophthalmic use of this product in children older than 1 year. It is recommended that feeding be withheld for four (4) hours after examination. Observe children closely for at least 30 minutes.

Cyclopentolate should be used with caution in children as convulsions including grand mal have been reported.

Necrotic colitis in premature children

Particular caution should be used when used in children because cases of necrotic colitis have been reported following administration of cyclopentolate eye drops in premature babies (see section 4.8). Early symptoms may include, but are not limited to, bradycardia, vomiting, food intolerance, increased stomach residues, abdominal distension, and bloody stools. In such a case, immediate medical evaluation is needed.

Parents are advised to avoid contact of the solution with the child's mouth and to wash their hands and the child's hands after administering the drops.

Use in the elderly

MINIMS® Cyclopentolate eye drops should be used with caution in elderly patients where increased intraocular pressure may be encountered and/or where they may be more susceptible to the CNS effects of cyclopentolate.

4.5 Interaction with other medicines and other forms of interaction

Although negligible cyclopentolate passes into the bloodstream after ocular instillation, medicine interactions are nevertheless possible.

The interactions observed with cyclopentolate administered by any route should therefore be taken into account.

Cyclopentolate may interfere with the antiglaucoma action of carbachol or pilocarpine; also, concurrent use of this medication may antagonise the antiglaucoma and miotic action of ophthalmic cholinesterase inhibitors.

4.6 Fertility, pregnancy and lactation

Pregnancy

Safety for use in pregnancy has not been established.

Breastfeeding

It is not known whether cyclopentolate and/or its metabolites are excreted in breast milk. Safety for use in lactation has not been established.

Fertility

No studies have been performed to evaluate the potential fertility impairing effects of cyclopentolate.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Local effects

Eye disorders

Local irritation may result following the use of this product. The frequency of this effect occurring is dependent on the concentration instilled.

Allergic conjunctivitis or blepharoconjunctivitis may rarely occur, manifesting as diffusely red eyes with lacrimation and itching.

Increased intraocular pressure may occur in predisposed patients.

Other local effects include: burning, photophobia, blurred vision, irritation, hyperaemia and punctate keratitis.

Systemic effects

Systemic cyclopentolate toxicity may be dose-related. Systemic adverse effects from cyclopentolate are not uncommon, especially in children, although this information is based on post-marketing reports for which frequencies are not accurately known.

Immune system disorders

Anaphylactic reaction and anaphylactic shock.

Nervous system disorders

Toxicity is usually transient and is manifested mainly by CNS disturbances. These reactions may include ataxia, seizures (especially in children), somnolence, incoherent speech, restlessness, hallucinations, hyperactivity, disorientation with regard to time and place, and failure to recognise people.

Peripheral effects atypical of anti-cholinergics, such as flushing or dryness of the skin and mucous membranes (mouth), as well as temperature changes have also been observed rarely with topical cyclopentolate in children and adults.

Other systemic effects include, urinary retention, vertigo, incoordination, giddiness, poor balance and tremor.

Cardiac disorders

Tachycardia

Gastrointestinal disorders

Necrotising colitis (in preterm infants), constipation, vomiting, gastroenteritis and feeding intolerance in infants.

Skin and subcutaneous tissue disorders

Skin rash

Paediatric population

The occurrence of systemic adverse effects is higher in children and infants.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit-risk of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the **"6.04 Adverse Drug Reactions Reporting Form"**, found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8

Suspected adverse reactions may also be reported directly to the Holder of the Certificate of registration using the following e-mail address:

PV-SouthAfrica@bauschhealth.com.

4.9 Overdose

Overdose is rare, but symptoms can include those mentioned under Section 4.8 above. Treatment is supportive, and as required to control symptoms of anticholinergic overdose. Specific therapies may be required, e.g. benzodiazepines for seizures.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 15.4 Ophthalmic preparation: Other

Mechanism of action

Cyclopentolate hydrochloride is a parasympatholytic medicine which paralyses the sphincter muscle of the iris, thus causing pupillary dilation (mydriasis); and also paralyses the ciliary muscle, thus causing paralysis of accommodation (cycloplegia).

5.2 Pharmacokinetic properties

Absorption

Cyclopentolate may be absorbed systemically either by transcorneal absorption, direct topical absorption through the skin or by absorption from the naso or naso-lacrimal system.

5.3 Preclinical safety data

No studies have been performed to evaluate the potential mutagenic, clastogenic o carcinogenic effects of cyclopentolate.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified water, hydrochloric acid (for pH adjustment)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

30 months

6.4 Special precautions for storage

Store in the refrigerator between 2 - 8 °C, protected from strong light. DO NOT FREEZE.

6.5 Nature and contents of container

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.

6.6 Special precautions for disposal

Each MINIMS® unit should be discarded after single use.

7 HOLDER OF CERTIFICATE OF REGISTRATION

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8 REGISTRATION NUMBER

C/15.4/49

9 DATE OF FIRST AUTHORISATION

26 August 1970

10 DATE OF REVISION OF THE TEXT

28 March 2023