

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Mydrilate 0.5% w/v Eye Drops

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Cyclopentolate Hydrochloride 0.5% w/v.

Contains 5 mg cyclopentolate hydrochloride per 1 ml.

Excipient(s) with known effect

Each millilitre contains 0.1 mg benzalkonium chloride.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye Drop Solution. (Eye Drops).

Clear colourless or almost colourless liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

- (i) Diagnostic purposes for fundoscopy and cycloplegic refraction.
- (ii) Dilating the pupil in inflammatory conditions of the iris and uveal tract.

4.2 Posology and method of administration

Posology

(i) Refraction / Fundoscopy

Adults (and the elderly):

One drop of 0.5% w/v solution instilled into the eye, repeated after 15 minutes if necessary, approximately 40 minutes before examination.

Deeply pigmented eyes may require the use of a 1% w/v solution. NB: maximum effect is reached after 30-60 minutes.

Children 6-16 years:

One drop of 1% w/v solution instilled into the eye, repeated after 15 minutes if necessary, approximately 40 minutes before examination.

Children under 6 years:

One or two drops of 1% w/v solution instilled into the eye, repeated after 15 minutes if necessary, approximately 40 minutes before examination.

(ii) For Uveitis, Iritis and Iridocyclitis

Adults and the elderly:

One or two drops of 0.5% w/v solution instilled into the eye up to 4 times daily or as required.

Deeply pigmented eyes may require the use of a 1% w/v solution.

Children:

At the discretion of the physician.

Paediatric population

Do not use during the first three months of life due to possible association between the cycloplegia produced and the development of amblyopia and also the increased risks of systemic toxicity in neonates.

The lowest possible dose and number of eye drops should be administered in infants. Close monitoring and supervision after instillation is advised.

Elderly population

No specific information on the use of this product in the elderly is available. Clinical trials have included patients over 65 years and no adverse reactions specific to this age group have been reported.

Method of administration

Instill directly into the eye.

To reduce systemic absorption the lacrimal sac should be compressed at the medial canthus by digital pressure for at least two minutes after instillation of the drops. This is especially advisable in children.

4.3 Contraindications

- (i) Use in narrow-angle glaucoma or those with a tendency towards glaucoma e.g. patients with a shallow anterior chamber.
- (ii) Hypersensitivity to cyclopentolate hydrochloride, benzalkonium chloride or any other components of the formulation listed in section 6.1.
- (iii) This preparation contains benzalkonium chloride and should not be used whilst soft contact lenses are being worn.
- (iv) Use in patients with paralytic ileus.
- (v) 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

Because of the risk of precipitating angle-closure glaucoma in the elderly and others prone to raised intraocular pressure, an estimate of the depth of the anterior chamber should be made before use, particularly if therapy is likely to be intense or protracted.

Caution should be observed when drugs of this group are administered to patients with prostatic enlargement, coronary insufficiency or cardiac failure, or ataxia. Atropine-like effects have been reported as side-effects.

Extreme caution is advised for use in children and individuals susceptible to belladonna alkaloids because of the increased risk of systemic toxicity.

Infants appear more likely to absorb eye drops into systemic circulation due to lower tear volume capacity. The risk of toxicity is further increased due to low body mass and immature cardiovascular and nervous systems. Use of mydriatic agents has been associated in preterm infants with increased difficulty feeding, abdominal distention, increased gastric aspirate and rare cases of necrotising enterocolitis. Convulsions in children have also been reported (see section 4.8).

Patients should be warned of the oral toxicity of this preparation, and advised to wash their hands after use. If accidentally swallowed, patients should be advised to seek medical attention.

Use with caution in an inflamed eye as the hyperaemia greatly increases the rate of systemic absorption through the conjunctiva.

4.5 Interaction with other medicinal products and other forms of interactions

The effects of anti-muscarinic agents may be enhanced by the concomitant administration of other drugs with antimuscarinic properties such as some antihistamines, butyrophenones, phenothiazines, tricyclic antidepressants and amantadine.

4.6 Fertility, pregnancy and lactation

There is insufficient evidence as to drug safety in pregnancy and lactation. This product should not be used during pregnancy unless it is considered essential by a physician.

4.7 Effects on ability to drive and use machines

May cause blurred vision, difficulty in focusing and sensitivity to light. Patients should be warned not to drive or engage in other hazardous activities (including climbing ladders and scaffolding) unless vision is clear. Complete recovery from the effects of Mydrilate Eye Drops may take up to 24 hours.

4.8 Undesirable effects

Frequencies are defined according to the following convention: very common ($\geq 1/10$), common $\geq 1/100$ to $1/10$, uncommon $\geq 1/1,000$ to $< 1/100$, rare ($\geq 1/10,000$ to $< 1/1,000$), very rare ($< 1/10,000$), not known (cannot be estimated from the available data).

System organ class	Adverse reactions	Frequency
Psychiatric disorders	abnormal behaviour ^a , psychotic disorders ^a	not known
Nervous system disorders	dizziness, convulsions ^b , partial seizures ^b	not known
Eye disorders	eye pain, increased intraocular pressure, eye oedema ¹ , eye irritation (stinging) ¹ , ocular hyperaemia ¹ , conjunctivitis ¹ , photophobia ²	not known
Cardiac disorders	bradycardia, tachycardia, palpitations, arrhythmia, cardiopulmonary failure ^a	not known
Vascular disorders	flushing	not known
Gastrointestinal disorders	dry mouth, vomiting, gastrointestinal hypomotility and constipation, abdominal distension ^c , necrotising enterocolitis ^d	not known
Skin and subcutaneous disorders	dry skin, skin rash ^a	not known
Renal and urinary disorders	urinary urgency, urinary retention, dysuria	not known
General disorders and administration site conditions	gait disturbance	not known

Notes

General

1. Following prolonged administrations
2. Secondary to pupillary dilation

Paediatric population

a. Abnormal behaviour, psychotic disorders, cardiopulmonary failure and skin rashes have been reported in the paediatric population.

- b. Convulsions and partial seizures have been reported in children but the frequency of these cases is not known based on the available data.
- c. Cases of abdominal distension have been reported in infants.
- d. Necrotising enterocolitis has been reported in preterm infants.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRAs Pharmacovigilance Website: www.hpra.ie.

4.9 Overdose

Systemic toxicity may occur following topical use, particularly in children. It is manifested by flushing and dryness of the skin (a rash may be present in children), blurred vision, a rapid and irregular pulse, fever, abdominal distension in infants, convulsions and hallucinations and the loss of neuromuscular co-ordination.

Treatment is supportive (there is no evidence that physostigmine is superior to supportive management). In infants and small children the body surface must be kept moist. If accidentally ingested, induce emesis or perform gastric lavage.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Cyclopentolate is an anti-muscarinic agent used topically in the eye as a mydriatic and cycloplegic. The effects are similar to those of atropine, but with a more rapid onset and a shorter duration of action.

5.2 Pharmacokinetic properties

Approximately 80% of any ocularly administered drops (26 microliter) is lost via the nasolacrimal duct, conjunctival blood vessels or spillage. Absorption via the nasolacrimal duct and conjunctival blood vessels occurs directly into the systemic circulation and bypasses initial entero-hepatic metabolism.

Cycloplegia following administration is quick in onset and short-lived. Maximal cycloplegia is achieved within 15-45 minutes of instillation and lasts on average about 20 minutes. Recovery normally takes place in about 4 hours, but very occasionally some effect persists for up to 24 hours.

Mydriasis is produced very rapidly and an average pupil diameter of 7 mm is usually reached 15-30 minutes after instillation of one drop of 0.5% solution. Complete recovery from the mydriatic effect generally occurs spontaneously in not more than 20 hours.

5.3 Preclinical safety data

Nothing stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Boric Acid
Potassium Chloride
Benzalkonium Chloride Solution
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened: 2 years

After first opening: 28 days

6.4 Special precautions for storage

Do not freeze. Keep the bottle in the outer carton in order to protect from light.

Before first opening: store at 2°C-8°C in a refrigerator.

Prior to first opening: remove from refrigerator and store at room temperature for 30 minutes.

After first opening: do not store above 25°C, do not refrigerate.

Discard 28 days after first opening.

Do not dilute or dispense from any container other than the original bottle.

6.5 Nature and contents of container

5ml dropper bottle of 0.5% w/v solution.

Bottle: LDPE, natural colour

Cap: Melamine, white colour

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

When using the product for the first time, screw down the cap firmly on the bottle to pierce the seal at the tip of the plastic nozzle and unscrew the cap for use.

7 MARKETING AUTHORISATION HOLDER

Esteve Pharmaceuticals GmbH,
Hohenzollerndamn 150-151,
14199 Berlin,
Germany

8 MARKETING AUTHORISATION NUMBER

PA22709/003/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st April 1979

Date of last renewal: 3rd February 2007

10 DATE OF REVISION OF THE TEXT

May 2022