# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Minims Cyclopentolate Hydrochloride 0.5%.
Minims Cyclopentolate Hydrochloride 1%.

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Clear, colourless, sterile eye drops containing cyclopentolate hydrochloride BP 0.5% w/v.
Clear, colourless, sterile eye drops containing cyclopentolate hydrochloride BP 1% w/v.

## 3 PHARMACEUTICAL FORM

Single-use, sterile eye drops.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

As a topical mydriatic and cycloplegic.

### 4.2 Posology and method of administration

*Adults (including the elderly):*
Instil dropwise into eye according to the recommended dosage.
One or two drops as required. Maximum effect is induced in 30 - 60 minutes after instillation.
For refraction and examination of the back of the eye: 1 drop of solution, which may be repeated after five minutes, is usually sufficient.
For anterior and posterior uveitis (if associated with signs of anterior uveitis) and for the breakdown of posterior synechiae: 1 - 2 drops are instilled every 6 - 8 hours.
Resistance to cycloplegia can occur in young children, in patients with dark skin and/or patients with dark irides, therefore, the strength of cyclopentolate used should be adjusted accordingly.

*Children*
< 3 months: Not recommended
3 months - 12 years: 1 drop of a 1% solution to each eye.
12 years - adult: 1 drop of 0.5% solution to each eye repeated after 10 minutes if necessary.
Children should be observed for 45 minutes after instillation.

## 4.3 Contraindications

Hypersensitivity to cyclopentolate or to any of the excipients listed in section 6.1.

Use in patients with narrow-angle glaucoma or those with a tendency towards glaucoma e.g., patients with a shallow anterior chamber (see section 4.4).

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

Tachycardia and cardiac symptoms are sometimes observed therefore the product should only be used with caution in patients with cardiovascular disease (e.g. tachycardias, heart failure).

Caution should be observed when cyclopentolate is administered to patients with epilepsy, ataxia, dementia, rhinitis sicca, gastrointestinal obstruction, toxic megacolon, myasthenia gravis, and obstructive urinary tract disorders.

Recovery of accommodation occurs within 24 hours (see section 4.7 and 5.1).

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

Systemic absorption 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).

Caution is advised in case of open-angle glaucoma. 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 (see section 4.3).

*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. The product should be used with caution in infants under the age of 1 year due to the increased risk of systemic toxicity.

Consider withholding feeding for four (4) hours after examination. Observe infants closely for at least 30 minutes.

Convulsions in children have also been reported in association with the use of cyclopentolate (see section 4.8).

*Necrotic colitis in premature children*
Particular caution should observed for use 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.

## 4.5 Interaction with other medicinal products and other forms of interaction

Since systemic cyclopentolate effects cannot be excluded even with topical application, the anticholinergic effects of other pharmaceuticals with anticholinergic activity could be increased (including but not limited to:antihistamines, butyrophenones, phenothiazines, tricyclic and tetracyclic antidepressants, amantadine, quinidine, disopyramide, oxybutynin).

Cyclopentolate may interfere with the ocular anti-hypertensive action of carbachol, pilocarpine, or ophthalmic cholinesterase inhibitors.

## 4.6 Fertility, pregnancy and lactation

The safety for use in pregnancy and lactation has not been established, therefore, use only when considered essential by the physician.

Pregnancy
There are no or limited amount of data from the use of cyclopentolate in pregnant women. Animal studies are insufficient with respect to reproductive toxicity.

As a precautionary measure, it is preferable to avoid the use of cyclopentolate eye drops during pregnancy.

Breast-feeding
It is not known how much cyclopentolate passes into breast milk. Infants can be very sensitive to anticholinergics. Therefore, the preparation should not be used during breastfeeding.

## 4.7 Effects on ability to drive and use machines

Cyclopentolate has major influence on the ability to drive and use machines. Cyclopentolate may cause transient blurring of vision on instillation. Warn patients not to drive or operate hazardous machinery until vision is clear.

## 4.8 Undesirable effects

Adverse reactions are listed in the table in frequency categories under MedDRA system/organ classes. The frequency of adverse reactions is defined using the following convention:
Very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥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 reaction |
|---|---|
| Eye disorders | |
| Not known | Eye irritation, accommodation disorder, eye pain, ocular hyperaemia, vision blurred, increased intraocular pressure, conjunctivitis |
| Gastrointestinal disorders | |
| Not known | Abdominal distension [a], constipation, dry mouth, nausea, vomiting, necrotising colitis [b] |
| Immune system disorders | |
| Rare | Allergic reaction |
| Not known | Hypersensitivity (both local and systemic hypersensitivity reactions) |
| Nervous system disorders | |
| Not known | Gait disturbance, dizziness, convulsions [c], seizures [c], cerebellar dysfunction, somnolence |
| Psychiatric disorders | |
| Not known | Hallucination, abnormal behaviour [d], psychotic disorder [d], |
| Cardiac disorders | |
| Not known | Arrhythmia, bradycardia, cardiopulmonary failure [d], palpitations, tachycardia |
| Vascular disorders | |
| Not known | Flushing |
| Skin and subcutaneous tissue disorders | |
| Not known | Dry skin, rash [d] |
| Renal and urinary disorders | |
| Not known | Urinary retention |

a. Cases of abdominal distension have been reported in infants.
b. Necrotising colitis has been reported in preterm infants.
c. Convulsions and seizures have been reported in children.
d. Abnormal behaviour, psychotic disorders, cardiopulmonary failure and rash have been reported in the paediatric population.

Systemic cyclopentolate toxicity is dose-related and would be less likely to occur following administration of 0.5% solution than following instillation of 1% solution.
Children are, however, more susceptible to such reactions than adults.

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 the Yellow

Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

## 4.9 Overdose

Overdose is rare but symptoms can include those mentioned in Section 4.8 above.

Symptoms
In isolated cases, ocular topical application of eye drops containing cyclopentolate can lead to central nervous system disorders and general systemic manifestations, especially in children.
a) Central nervous manifestations: abnormal behaviour (restlessness, incoherent speech, disorientation), hallucinations, memory loss, gait disturbance, seizures, somnolence.
b) General systemic manifestations: dry mouth, flushing, tachycardia, increase in temperature, urinary blockage.

Treatment
Treatment is supportive and symptomatic.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Ophtalmologicals, mydriatics and cycloplegics, Anticholinergics
ATC code: SO1FA04

Cyclopentolate hydrochloride is a synthetic tertiary amine, antimuscarinic compound with actions similar to atropine.

### 5.2 Pharmacokinetic properties
As a group, the synthetic tertiary amine antimuscarinic compounds are well absorbed following oral administration. Cyclopentolate may be absorbed systemically either by transcorneal absorption, direct topical absorption through the skin or by absorption from the nasal or naso lacrimal system.

### 5.3 Preclinical safety data
There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients
Hydrochloric acid
Purified water

## 6.2 Incompatibilities

None known.

### 6.3 Shelf life
15 months.

### 6.4 Special precautions for storage
Store below 25ºC. Do not freeze. Protect from light.

**6.5 Nature and contents of container**
A sealed, conical shaped container fitted with a twist and pull-off cap. Each Minims unit is overwrapped in an individual polypropylene/paper pouch. Each container holds approximately 0.5ml of solution.

### 6.6 Special precautions for disposal and other handling

Each Minims unit should be discarded after a single use.

## 7 MARKETING AUTHORISATION HOLDER

Bausch & Lomb UK Limited
Bausch & Lomb House
106 London Road
Kingston-Upon-Thames
Surrey, UK
KT2 6TN

## 8 MARKETING AUTHORISATION NUMBERS

Minims Cyclopentolate Hydrochloride 0.5%: PL 03468/0070
Minims Cyclopentolate Hydrochloride 1%: PL 03468/0071

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first Authorisation: 17 June 1987
Date of Renewal of Authorisation:
Minims Cyclopentolate Hydrochloride 0.5%: 17 June 1992
Minims Cyclopentolate Hydrochloride 1%: 25 July 1997

## 10 DATE OF REVISION OF THE TEXT

09/04/2024