Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Minims Cyclopentolate Hydrochloride 1% w/v Eye Drops, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Cyclopentolate Hydrochloride 1.0% w/v.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Eye drops, solution
Single-use, clear, colourless, sterile solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

As a topical mydriatic and cycloplegic agent. Preoperative use in ophthalmic surgery. Refraction and treatment of iritis and iridocyclitis. Minims Cyclopentolate is indicated in adults and children over the age of 1 years.

4.2 Posology and method of administration

Posology
Resistance to cycloplegia can occur in patients with dark skin and/or patients with dark irides, therefore the dose of cyclopentolate used should be adjusted accordingly. The lowest possible dose and number of eye drops should be administered. Close monitoring and supervision after instillation is advised.

Adults (including the elderly)
Instil dropwise into eye according to the recommended dosage.

For mydriasis: the recommended dosage in adults is one drop of the 1% solution.

For refraction: 1 drop of solution, which may be repeated after five minutes, is usually sufficient. For iritis and iridocyclitis: 1-2 drops are instilled every six to eight hours.

Children over 12 months of age and adolescents
For mydriasis and refraction: 1-2 drops of solution, which may be repeated after 5-10 minutes.

For iritis and iridocyclitis: To be used only at the discretion of the physician.

Children below 12 months of age
Cyclopentolate 1% should not be used in premature infants and neonates due to increased risk of systemic toxicity; alternative strengths of cyclopentolate or other mydriatic agents may be considered (see Section 4.3).

Use of cyclopentolate 1% is not recommended for use in children younger than the age of 12 months. Data on the safety and appropriate posology of cyclopentolate in children under the age of 12 months are limited, and this age group may be most susceptible to systemic absorption and unintended serious anticholinergic effects. Alternative strengths of cyclopentolate, or other mydriatic agents should be considered for children under the age of 12 months.

Method of administration
Ocular use.

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 nasolacrimal duct to the wide absorptive area of the nasal and pharyngeal mucosa. It is especially advisable in children.

4.3 Contraindications

Do not use in patients with a known hypersensitivity to cyclopentolate or to any of the excipients listed in section 6.1.
Cyclopentolate 1% should not be used in premature infants and neonates due to increased risk of systemic toxicity (see Section 4.2).
Do not use in patients with paralytic ileus.
Do not use in patients with narrow-angle glaucoma, or those with a tendency towards glaucoma, e.g., with a shallow anterior chamber.

4.4 Special warnings and precautions for use

Caution is advised in inflamed or hyperaemic eye as increased systemic absorption may occur.

Due to potential systemic anticholinergic effects of cyclopentolate, caution is advised in case of

- epilepsy,
- prostate disorders,
- ataxia,
- senile dementia,
- rhinitis sicca,
- mechanical stenosis of the gastrointestinal tract,
- toxic megacolon,
- myasthenia gravis
- obstructive urinary tract disorders.

Caution is advised in elderly as they can be particularly sensitive to the anticholinergic action of cyclopentolate.

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*). Caution is advised in case of open-angle glaucoma.

Tachycardia and cardiac symptoms are sometimes observed, therefore the product should be used with caution in patients with cardiovascular disease.

Paediatric population
Atropine-like effects have been reported as side effects with cyclopentolate 1% and particular caution is advised for use in children because of the increased risk of systemic toxicity. The lowest possible dose should always be used when dosing children with cyclopentolate 1%, and use should be under the care of a specialist.

Minims Cyclopentolate 1% is contraindicated in premature infants and neonates due to the increased risk of systemic toxicity (*see section 4.3)*. Minims cyclopentolate 1% is not recommended in children under the age of 12 months (*see Section 4.2*). Alternative cyclopentolate strengths or other mydriatic agents may be available for use in premature infants, neonates and children under the age of 12 months.

Minims cyclopentolate 1% should be used with extreme caution in children 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, 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. These disturbances include ataxia, incoherent speech, restlessness, hallucinations, hyperactivity, seizures, disorientation as to time and place and failure to recognise people. Observe children closely for at least 30 minutes.

Contact lenses
It is advised to remove contact lenses prior to the administration of the drops. There is no information on the effect of this product on contact lenses. Therefore, contact lenses should not be worn until the effects of the drops have completely worn off.

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 (e.g. antihistamines, phenothiazines, tricyclic and tetracyclic antidepressants, amantadine, quinidine, disopyramide, metoclopramide) could be increased.
Cyclopentolate may interfere with the ocular anti-hypertensive action of carbachol, pilocarpine, or ophthalmic cholinesterase inhibitors.
The mydriatic effect of cyclopentolate hydrochloride is ended by the use of parasympathomimetic drugs such as physostigmine or pilocarpine.

4.6 Fertility, pregnancy and lactation

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 a marked effect on the ability to drive and use machines. Cyclopentolate may cause temporary blurred vision (*see section 4.8*). Recovery of accommodation occurs usually within 24 hours.

Patients should not drive or operate machinery until vision is clear.

4.8 Undesirable effects

Tabulated list of adverse reactions
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).

MedDRA system organ class	**Adverse Reaction**
Eye disorders	
Common	Eye irritation, ocular stinging on instillation
Not known	Ocular hyperaemia, eye oedema, accommodation disorder, angle closure glaucoma, eye pain, vision blurred, visual impairment.
Gastrointestinal disorders	
Common	Gastrointestinal hypomotility leading to constipation
Not known	Abdominal distension (in infants), constipation, dry mouth, nausea, vomiting, necrotising colitis (in preterm infants)
General disorders and administration site conditions	
Common	Fever
Not known	Mucosal dryness
Immune system disorders	
Rare	Allergic reaction
Not known	Hypersensitivity (both local and systemic hypersensitivity reactions), anaphylactic reaction, anaphylactic shock
Nervous system disorders	

Not known	Drowsiness, seizures (especially in children), ataxia, balance disorder, central nervous system disturbances, cerebellar dysfunction, dizziness, dysarthria, incoherent speech (in children), somnolence, psychomotor hyperactivity
Psychiatric disorders	
Common	Confusion, hallucinations
Not known	Psychotic disorder, abnormal behaviour especially in children, agitation, disorientation, restlessness.
Skin and subcutaneous tissue disorders	
Not known	Skin rash, dry skin, erythema
Vascular disorders	
Common	Facial flushing
Investigations	
Not known	Intraocular pressure increased
Infections and infestations	
Not known	Conjunctivitis
Cardiac disorders	
Not known	Arrhythmia, bradycardia, cardiopulmonary failure, palpitations, tachycardia
Renal and urinary disorders	
Not known	Urinary retention

Paediatric population
Systemic cyclopentolate toxicity is dose-related and children are more susceptible to such reactions than adults.

- Abnormal behaviour, psychotic disorders, cardiopulmonary failure and skin rashes have been reported in the paediatric population.
- Drowsiness, seizures and incoherent speech have been reported in children.
- Cases of abdominal distension have been reported in infants.
- 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:
HPRA Pharmacovigilance
Website: www.hpra.ie

4.9 Overdose

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 with central nervous system disorders.

1. Central nervous manifestations: restlessness, incoherent speech, optical hallucinations, memory loss, disorientation, ataxia, very rarely epileptiform seizures, exhaustion, sleep.
2. General systemic manifestations: dry mouth, flushing of the face, tachycardia, increase in temperature, urinary blockage, pupil dilation, loss of accommodation.

Treatment
Treatment is supportive and symptomatic. Physostigmine or pilocarpine can be administered as an antidote.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: ATC code: SO1FA04: Ophtalmologicals, mydriatics and cycloplegics, cyclopentolate

Mechanism of action
Cyclopentolate hydrochloride is a competitive antagonist of acetylcholine at the parasympathetic nerve endings.

5.2 Pharmacokinetic properties

Absorption
Cyclopentolate is 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 (for pH adjustment)
Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

15 months

6.4 Special precautions for storage

Store below 25^{o}C. Do not freeze. Store in the original container in order to protect from light.

6.5 Nature and contents of container

A sealed conical shaped container with a twist and pull off cap made from Ph. Eur. Grade polypropylene for containers and closures for parenteral and ophthalmic preparations.
Each Minims unit is overwrapped in an individual polypropylene/paper pouch. Each container holds approximately 0.5ml of solution. Each carton contains 20 Minims units.

6.6 Special precautions for disposal

For single use only. Discard any remaining solution.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Bausch + Lomb Ireland Limited
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Dublin 24
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Ireland

8 MARKETING AUTHORISATION NUMBER

PA23259/011/001

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10 DATE OF REVISION OF THE TEXT

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