

**CYCLOPENTOLATE HYDROCHLORIDE 0.5% W/V EYE DROPS
SOLUTION
PL 17509/0012**

**CYCLOPENTOLATE HYDROCHLORIDE 1.0% W/V EYE DROPS
SOLUTION
PL 17509/0013**

UKPAR

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LAY SUMMARY

The MHRA granted Intraparm Laboratories Limited Marketing Authorisations (licences) for the medicinal products Cyclopentolate Hydrochloride 0.5% w/v Eye Drops Solution (PL 17509/0012) and Cyclopentolate Hydrochloride 1.0% w/v Eye Drops Solution (PL 17509/0013) on 11th January 2007. These are prescription-only medicines (POM) for use in diagnostic eye examinations and to treat some types of eye inflammation (uveitis, iritis and iridocyclitis).

Cyclopentolate Hydrochloride Eye Drops Solution contains the active ingredient cyclopentolate hydrochloride, which belongs to a group of drugs called cycloplegics and mydriatic drugs. These paralyse the ciliary muscles of the eye and cause the pupil of the eye to dilate.

These applications are duplicates of previously granted applications for Mydrilate 0.5% Eye Drops (PL 17509/0007) and Mydrilate 1.0% Eye Drops (PL 17509/0008), licensed to Intraparm Laboratories.

No new or unexpected safety concerns arose from these simple applications and it was, therefore, judged that the benefits of using Cyclopentolate Hydrochloride 0.5% w/v Eye Drops Solution and Cyclopentolate Hydrochloride 1.0% w/v Eye Drops Solution outweigh the risks, hence Marketing Authorisations have been granted.

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SCIENTIFIC DISCUSSION

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INTRODUCTION

The UK granted marketing authorisations for the medicinal products Cyclopentolate Hydrochloride 0.5% w/v Eye Drops Solution (PL 17509/0012) and Cyclopentolate Hydrochloride 1.0% w/v Eye Drops Solution (PL 17509/0013) to Intraparm Laboratories Limited on 11th January 2007. The products are prescription-only medicines.

The applications were submitted as simple abridged applications according to Article 10c of Directive 2001/83/EC, cross-referring to Mydrilate 0.5% w/v Eye Drops (PL 17509/0007) and Mydrilate 1.0% w/v Eye Drops (PL 17509/0008), which were previously owned by WB Pharmaceuticals Limited (February 1990 to December 1999) and Boehringer Ingelheim Limited (December 1999 to August 2001, PL 00015/0200-1) before the licences were transferred to Intraparm Laboratories Limited as a Change of Ownership.

No new data was submitted nor was it necessary for these simple applications, as the data is identical to that of the previously granted cross-reference products. As the cross-reference products were granted prior to the introduction of current legislation, no PARs were generated for them.

The products contain the active ingredient cyclopentolate hydrochloride, which is a cycloplegic and mydriatic agent. Cyclopentolate Hydrochloride 0.5% w/v and 1.0% w/v Eye Drops Solution are indicated in diagnostic purposes for fundoscopy and cycloplegic refraction, and for dilating the pupil in inflammatory conditions of the iris and uveal tract.

These applications for Cyclopentolate Hydrochloride 0.5% w/v and 1.0% w/v Eye Drops Solution were submitted at the same time and were assessed concurrently. Consequently, all sections of this Scientific Discussion refer to both products.

PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 17509/0012-3
PROPRIETARY NAME: Cyclopentolate Hydrochloride 0.5% w/v Eye Drops Solution
Cyclopentolate Hydrochloride 1.0% w/v Eye Drops Solution
ACTIVE(S): Cyclopentolate hydrochloride
COMPANY NAME: Intrapharm Laboratories Limited
E.C. ARTICLE: Article 10c of Directive 2001/83/EC
LEGAL STATUS: POM

1. INTRODUCTION

These are simple, piggy back applications for Cyclopentolate Hydrochloride 0.5% w/v Eye Drops Solution and Cyclopentolate Hydrochloride 1.0% w/v Eye Drops Solution submitted under Article 10c of Directive 2001/83/EC. The proposed MA holder is “Intrapharm Laboratories Limited, 60 Boughton Lane, Maidstone, Kent, ME15 9QS”.

These applications cross refer to standard abridged applications for Mydrilate 0.5% w/v Eye Drops (PL 17509/0007) and Mydrilate 1.0% w/v Eye Drops (PL 17509/0008), which are currently registered in the UK. These applications are considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 Name(s)

The proposed names of the products are Cyclopentolate Hydrochloride 0.5% w/v Eye Drops Solution and Cyclopentolate Hydrochloride 1.0% w/v Eye Drops Solution. The products have been named in line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes

The products contain cyclopentolate hydrochloride, equivalent to 0.5% w/v and 1.0% w/v of cyclopentolate hydrochloride, respectively. They are to be stored in dropper container made of low density polyethylene with a cap, in a pack size of 5ml for both strengths. The proposed shelf-life (2 years unopened and 28 days after opening) and storage conditions (Avoid freezing, store in refrigerator [2-8 degrees C], and keep container in outer carton) are consistent with the details registered for the cross-reference products.

2.3 Legal status

On approval, the products will be subject to a medical prescription.

2.4 Marketing authorisation holder/Contact Persons/Company

The proposed Marketing Authorisation holder is Intrapharm Laboratories Limited, 60 Boughton Lane, Maidstone, Kent, ME15 9QS.

The QP responsible for pharmacovigilance is stated and his CV is included.

2.5 Manufacturers

The proposed manufacturing sites are consistent with those registered for the cross-reference products and evidence of GMP compliance has been provided.

2.6 Qualitative and quantitative composition

The proposed compositions are consistent with the details registered for the cross-reference products.

2.7 Manufacturing process

The proposed manufacturing process is consistent with the details registered for the cross-reference products and the maximum batch size is stated.

2.8 Finished product/shelf-life specification

The proposed finished product specification is in line with the details registered for the cross-reference products.

2.9 Drug substance specification

The proposed drug substance specification for each product is consistent with the details registered for the cross-reference products.

2.10 TSE Compliance

No materials of animal or human origin are included in the product.

3. EXPERT REPORTS

The applicant has included detailed expert reports in Module 2 of the application. Signed declarations and copies of the experts' CVs are enclosed in Module 1.4 for the quality, non-clinical and clinical experts. All are considered to have sufficient experience for their responsibilities.

4. PRODUCT NAME & APPEARANCE

See 2.1 for details of the proposed product names. The appearances of the products are identical to the cross-reference products.

5. SUMMARY OF PRODUCT CHARACTERISTICS

The proposed SmPCs are consistent with the details registered for the cross-reference products.

6. PATIENT INFORMATION LEAFLET/CARTON

PIL

The patient information leaflet has been prepared in-line with the details registered for the cross-reference products.

Carton and blister

The proposed artwork is comparable to the artwork registered for the cross-reference product and complies with statutory requirements. In line with current legislation the applicant has also included the name of the product in Braille on the outer packaging and has included sufficient space for a standard UK pharmacy dispensing label.

7. CONCLUSIONS

The data submitted with the applications are acceptable. Marketing Authorisations should be granted.

PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with these applications and none are required for applications of this type.

CLINICAL ASSESSMENT

As these are duplicate applications to Mydrilate 0.5% w/v Eye Drops (PL 17509/0007) and Mydrilate 1.0% w/v Eye Drops (PL 17509/0008), no new clinical data have been supplied and none are required.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The data for these applications are consistent with that previously assessed for the cross-reference products and as such has been judged to be satisfactory.

PRECLINICAL

No new preclinical data were submitted and none are required for applications of this type.

EFFICACY

Cyclopentolate hydrochloride is a well-known drug and has been used as a cycloplegic and mydriatic agent for many years. These applications are identical to previously granted applications for Mydrilate 0.5% w/v Eye Drops (PL 17509/0007) and Mydrilate 1.0% w/v Eye Drops (PL 17509/0008), which were approved on February 1990.

No new or unexpected safety concerns arise from these applications.

The SPC, PIL and labelling are satisfactory and consistent with those for the cross-reference products.

RISK BENEFIT ASSESSMENT

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant's products are identical to the cross-reference products which have been licensed in the UK since 1981. Extensive clinical experience with cyclopentolate hydrochloride is considered to have demonstrated the therapeutic value of the compound. The risk benefit is, therefore, considered to be positive.

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STEPS TAKEN FOR ASSESMENT

1	The MHRA received the marketing authorisation application on 18 th May 2005.
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 13 th June 2005.
3	Following assessment of the application the MHRA requested further information on 21 st July 2005 and 21 st April 2006.
4	The applicant responded to the MHRA's requests, providing further information on 31 st March 2006 and 12 th May 2006
5	The application was determined on 11 th January 2007

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STEPS TAKEN AFTER ASSESSMENT

Date submitted	Application type	Scope	Outcome

**CYCLOPENTOLATE HYDROCHLORIDE 0.5% W/V EYE DROPS
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PL 17509/0012**

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Cyclopentolate Hydrochloride 0.5 % w/v Eye Drops, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Cyclopentolate Hydrochloride 0.5 % w/v.

For full list of excipients, see 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution.

A clear, colourless, or almost colourless liquid free from particulate matter

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

For ocular use.

When using the product for the first time, screw down firmly to pierce the seal at the tip of the nozzle.

(i) Refraction / Fundoscopy

Adults (and the elderly):

One drop of 0.5 % 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 % solution.

NB: Maximum effect is reached after 30-60 minutes.

Children 6-16 years:

One drop of 1 % 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 % 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 % solution instilled into the eye up to 4 times daily or as required.

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

Children:

At the discretion of the physician.

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.

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.

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.

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.
- (iii) This preparation contains benzalkonium chloride and should not be used whilst soft contact lenses are being worn; wait at least 15 minutes after removal of contact lenses prior to application..
- (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.

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.

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.

4.5 Interaction with other medicinal products and other forms of interaction

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

4.6 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 Cyclopentolate Hydrochloride 0.5 % w/v Eye Drops, solution may take up to 24 hours.

4.8 Undesirable effects

(i) Local:

Common: increased intraocular pressure, transient stinging, and sensitivity to light secondary to pupillary dilation, conjunctivitis.

Less commonly: prolonged administration may lead to local irritation, hyperaemia and oedema

(ii) Systemic:

Systemic anticholinergic toxicity may occur with prolonged use. Dryness of the mouth, flushing, dryness of the skin, bradycardia followed by tachycardia with palpitations and arrhythmias, urinary urgency, difficulty and retention, reduction in the tone and motility of the gastrointestinal tract leading to constipation have been reported.

(iii) Rarer cases of vomiting, giddiness and staggering have been reported.

(iv) In children, rarer cases of rash have been reported. Very rarely psychotic reactions, behavioural disturbances and cardio-respiratory collapse may occur. In infants abdominal distension has been reported in isolated cases.

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

ATC code: S01FA04

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

None stated

5.3 Preclinical safety data

None 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

2 years.

After first opening the container, 28 days

6.4 Special precautions for storage

Store at 2-8°C. Store in a refrigerator. Do not freeze. Keep bottle in the outer carton. Do not dilute or dispense from any container other than the original bottle

6.5 Nature and contents of container
5 ml dropper bottle of 0.5 % solution.
Bottle: LE 6601 PH (LDPE)
Natural colour
Cap White melamine or white polypropylene

6.6 Special precautions for disposal
Not applicable.

7 MARKETING AUTHORISATION HOLDER

Intrapharm Laboratories Ltd
60 Boughton Lane
Maidstone
Kent
ME15 9QS
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 17509/0012

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

11/01/2007

10 DATE OF REVISION OF THE TEXT

11/01/2007

CYCLOPENTOLATE HYDROCHLORIDE 1.0% W/V EYE DROPS SOLUTION

PL 17509/0013

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Cyclopentolate Hydrochloride 1.0 % w/v Eye Drops, solution.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Cyclopentolate Hydrochloride 1.0 % w/v.

For a full list of excipients, see 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution.

A clear, colourless, or almost colourless liquid free from particulate matter.

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

For ocular use.

When using the product for the first time, screw down firmly to pierce the seal at the tip of the nozzle.

(i) Refraction / Fundoscopy

Adults (and the elderly):

One drop of 0.5 % 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 % solution.

NB: Maximum effect is reached after 30-60 minutes.

Children 6-16 years:

One drop of 1 % 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 % 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 % solution instilled into the eye up to 4 times daily or as required.

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

Children:

At the discretion of the physician.

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.

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.

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.

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.
- (iii) This preparation contains benzalkonium chloride and should not be used whilst soft contact lenses are being worn; wait at least 15 minutes after removal of contact lenses prior to application.
- (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.

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.

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

4.5 Interaction with other medicinal products and other forms of interaction

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

4.6 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 Cyclopentolate Hydrochloride Eye Drops, solution may take up to 24 hours.

4.8 Undesirable effects

(i) Local:

Common: increased intraocular pressure, transient stinging, and sensitivity to light secondary to pupillary dilation, conjunctivitis.

Less commonly: prolonged administration may lead to local irritation, hyperaemia and oedema.

(ii) Systemic:

Systemic anticholinergic toxicity may occur with prolonged use. Dryness of the mouth, flushing, dryness of the skin, bradycardia followed by tachycardia with palpitations and arrhythmias, urinary urgency, difficulty and retention, reduction in the tone and motility of the gastrointestinal tract leading to constipation have been reported.

(iii) Rarer cases of vomiting, giddiness and staggering have been reported.

(iv) In children, rarer cases of rash have been reported. Very rarely psychotic reactions, behavioural disturbances and cardio-respiratory collapse may occur. In infants abdominal distension has been reported in isolated cases.

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

ATC code: S01F A 04

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

None stated.

5.3 Preclinical safety data

None 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

Not applicable.

After first opening the container, 28 days.

6.4 Special precautions for storage

Store at 2-8°C. Store in a refrigerator. Do not freeze. Keep bottle in the outer carton.
Do not dilute or dispense from any container other than the original bottle.

6.5 Nature and contents of container

5 ml dropper bottle of 1.0 % solution.

Bottle: LE 6601 PH (LDPE)

Natural colour

Cap White melamine or white polypropylene

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

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60 Boughton Lane

Maidstone

Kent

ME15 9QS

United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

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9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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CYCLOPENTOLATE HYDROCHLORIDE 1.0% W/V EYE DROPS SOLUTION PL 17509/0013

PRODUCT INFORMATION LEAFLET

Cyclopentolate Hydrochloride 0.5 % w/v Eye Drops, solution
Cyclopentolate Hydrochloride 1.0 % w/v Eye Drops, solution



PATIENT INFORMATION LEAFLET

What You Should Know About Cyclopentolate Hydrochloride Eye Drops

Please read this leaflet carefully before you start to use your medicine. It contains a summary of the information available on your medicine. The information in the leaflet applies to Cyclopentolate Hydrochloride Eye Drops only. If after reading this you have any questions ask your doctor or pharmacist.

The name of your medicine is Cyclopentolate Hydrochloride Eye Drops.

Each 5ml bottle of eye drops contains either a 0.5% w/v or a 1.0% w/v solution of Cyclopentolate Hydrochloride as the active ingredient.

The eye drops also contain the following inactive ingredients: benzalkonium chloride solution, boric acid, potassium chloride and water.

Cyclopentolate Hydrochloride Eye Drops 0.5% w/v and 1.0% w/v are available in 5ml dropper bottles.

Cyclopentolate Hydrochloride Eye Drops belong to a group of medicines called cycloplegic and mydriatic agents which paralyse the ciliary muscles of the eye (makes focussing difficult) and causes the pupil of the eye to dilate.

Marketing Authorisations in the UK and Ireland are held by:
Intrapharm Laboratories Ltd, Maidstone, Kent ME15 9QS. UK

The Manufacturer is:
Holopack Verpackungstechnik GmbH
Bahnhofstraße, D-74429 Sulzbach-Laufen
Germany

How Cyclopentolate Hydrochloride Eye Drops Help You

Cyclopentolate Hydrochloride Eye Drops are used in diagnostic eye examinations (e.g. refraction tests and fundoscopy) and also to treat some types of eye inflammation (e.g. uveitis, iritis and iridocyclitis).

Before Using Cyclopentolate Hydrochloride Eye Drops

Tell your doctor or pharmacist if:

- You are pregnant, likely to become pregnant or if you are breast feeding.
- You suffer from glaucoma or have a tendency towards glaucoma, your optician will advise you if this is the case.
- You are hypersensitive or allergic to cyclopentolate hydrochloride, benzalkonium chloride or any other ingredients listed above.
- Your child for whom the drops are intended, suffers from brain damage, acquired before or after birth, particularly if this is associated with a tendency to epileptic fits
- You are hypersensitive or allergic to other atropine like drugs.
- You wear soft contact lenses. Cyclopentolate Hydrochloride Eye Drops contain benzalkonium chloride and should not be used whilst soft contact lenses are being worn; wait at least 15 minutes after removal of contact lenses prior to application.
- You have or suffer from paralytic ileus (blockage of the small intestine due to loss of gut movement).
- You are a man with an enlarged prostate gland.
- You suffer from heart problems especially angina, heart attacks or heart failure.
- You are taking other medicines which have antimuscarinic effects such as: antihistamines, antidepressants or drugs used in other mental illness (eg phenothiazines or butyrophenones) or amantadine (for Parkinson's disease).
- You have an inflamed eye(s) (inflammation may mean that more of the eye drops are absorbed into the bloodstream).

If in doubt ask your doctor or pharmacist

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How To Use Your Eye Drops

Follow your doctor's instruction about what and how to use your eye drops and always read the label.

When using the pack 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. Replace the cap after use.

To reduce absorption into the blood stream the "lacrimal sac" should be compressed by applying pressure just beneath the punctum of the eye. Ask your doctor how to do this.

In **Refraction Tests** and **Fundoscopy** (diagnostic eye examinations) Cyclopentolate Hydrochloride Eye Drops will normally be given as follows:

Adults and the elderly: 1 drop of a 0.5% w/v solution instilled into the eyes, repeated after 15 minutes if necessary, approximately 40 minutes before the examination. Deeply pigmented eyes may require the use of 1% w/v solution.

Children 6 to 16 years: 1 drop of a 1% w/v solution instilled into the eye, repeated after 15 minutes if necessary, approximately 40 minutes before the examination.

Children under 6 years: 1 or 2 drops of a 1% w/v solution instilled into the eye, repeated after 15 minutes, approximately 40 minutes before eye examination.

In **Inflammatory Conditions of the Eye** Cyclopentolate Hydrochloride Eye Drops are normally used as follows:

Adults and the elderly: 1 or 2 drops of a 0.5% w/v solution up to four times daily or as required. Deeply pigmented eyes may require the use of a 1% w/v solution.

Children: Follow the instruction given by the doctor.

CYCLOPENTOLATE HYDROCHLORIDE EYE DROPS SHOULD NOT BE USED FOR BABIES UNDER 3 MONTHS OF AGE

CYCLOPENTOLATE HYDROCHLORIDE EYE DROPS MAY CAUSE SIDE-EFFECTS IF SWALLOWED, THEREFORE MAKE SURE YOU WASH YOUR HANDS AFTER USE. IF THE EYE DROPS ARE SWALLOWED ACCIDENTALLY, SEEK MEDICAL ADVICE IMMEDIATELY.

If you use more of your Eye Drops than you should.

It is very unlikely that you will suffer an overdose after using this Cyclopentolate Hydrochloride Eye Drops. However if you do suddenly feel unwell or if you are worried, you should contact your doctor or the nearest casualty department immediately.

If you forget to take a dose of your Eye Drops

If you forget to take a dose of Cyclopentolate Hydrochloride Eye Drops, use it as soon as you remember then carry on taking it as before.

After Using Your Eye Drops

Like all medicines Cyclopentolate Hydrochloride Eye Drops can have side-effects. It may cause the following effects on the eye; an increased pressure within the eyeball, temporary stinging, blurred vision, difficulty in focussing and sensitivity to light.

If vision is affected do not drive or operate machinery or carry out other hazardous activities e.g. climbing ladders or scaffolding until vision returns to normal. Complete recovery may take up to 24 hours.

Prolonged administration may lead to irritation of the eye, hyperaemia (excess blood in the vessels of the eye), oedema (excess fluid in the eye) and conjunctivitis (inflammation of the conjunctiva). Other side-effects which may occur are a dry mouth, flushing of the skin, dryness of the skin, an irregular heart rate, palpitations, urinary urgency, difficulty in passing urine, constipation and vomiting with giddiness and staggering. In addition, in children, rash, psychiatric and behavioural disturbances, and collapse affecting breathing, heart rate and blood pressure may occur. Bloating stomach may occur in infants.

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

How to Store Your Medicine

Cyclopentolate Hydrochloride Eye Drops should be stored at 2-8°C. Store in a refrigerator. Do not freeze. Keep bottle in the outer carton in order to protect from light. Do not dilute or dispense from any container other than the original bottle. Discard 28 days after opening.

Keep out of the reach and sight of children.

Do not use the eye drops after the expiry date which you will find printed on the packaging.

This leaflet was revised in August 2005.

REMEMBER THIS MEDICINE IS FOR YOU. Only a doctor can prescribe it for you. NEVER give it to others as it may harm them, even if their symptoms are the same as yours.

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578936/GB/3

**CYCLOPENTOLATE HYDROCHLORIDE 0.5% W/V EYE DROPS
SOLUTION
PL 17509/0012**

LABELLING

**Cyclopentolate Hydrochloride
0.5% w/v Eye Drops, solution.**

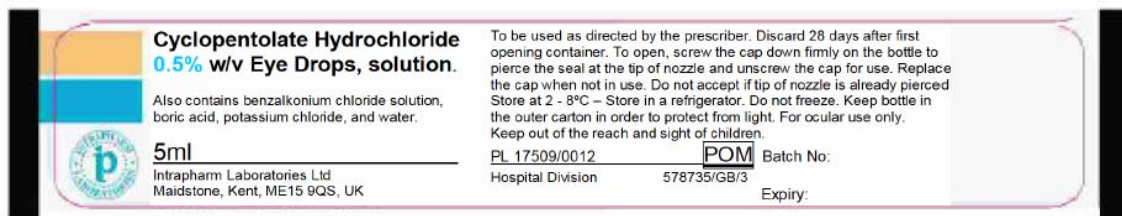
Also contains benzalkonium chloride solution,
boric acid, potassium chloride, and water.

5ml

Intrapharm Laboratories Ltd
Maidstone, Kent, ME15 9QS, UK

To be used as directed by the prescriber. Discard 28 days after first opening container. To open, screw the cap down firmly on the bottle to pierce the seal at the tip of nozzle and unscrew the cap for use. Replace the cap when not in use. Do not accept if tip of nozzle is already pierced. Store at 2 - 8°C – Store in a refrigerator. Do not freeze. Keep bottle in the outer carton in order to protect from light. For ocular use only. Keep out of the reach and sight of children.

PL 17509/0012 **POM** Batch No:
Hospital Division 578735/GB/3
Expiry:



**CYCLOPENTOLATE HYDROCHLORIDE 1.0% W/V EYE DROPS
SOLUTION
PL 17509/0013**

LABELLING

**Cyclopentolate Hydrochloride
1.0% w/v Eye Drops, solution.**

Also contains benzalkonium chloride solution,
boric acid, potassium chloride, and water.

5ml

Intrapharm Laboratories Ltd
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