

IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PA0290/002/001

Case No: 2070171

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Alcon Laboratories (UK) Ltd

Pentagon Park, Boundary Way, Hemel Hempstead, Hertfordshire HP2 7UD, England

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Mydriacyl 0.5% w/v eye drops, solution

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **02/09/2009**.

Signed on behalf of the Irish Medicines Board this

A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Mydriacyl 0.5% w/v eye drops, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Tropicamide 0.5 % w/v.

Excipients: Benzalkonium chloride 0.01% w/v

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution

A clear and colourless solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Tropicamide is a short acting anticholinergic agent used as a mydriatic and cycloplegic. It is indicated for topical use for:

Diagnostic purposes for fundoscopy and cycloplegic refraction.

4.2 Posology and method of administration

Adults, elderly and children:

Fundoscopy:

One or two drops of 0.5% solution instilled into the eye(s) 15 to 20 minutes prior to examination. Individuals with heavily pigmented irises may require larger doses.

Cycloplegic Refraction:

One or two drops of 1% solution instilled into the eye(s) repeated after 5 minutes. If the patient is not seen within 20 to 30 minutes an additional drop may be instilled to prolong the mydriatic effect.

Tropicamide has been reported to be inadequate for cycloplegia in children. A more powerful cycloplegic agent such as atropine may be required.

4.3 Contraindications

Contra-indicated in closed or narrow-angle glaucoma and in persons showing hypersensitivity to any component of this preparation.

Mydriacyl 0.5% is preserved with benzalkonium chloride, which may cause eye irritation. Benzalkonium chloride is known to discolour soft contact lenses and should not be used when the patient is wearing contact lenses.

Contact lenses should be removed prior to application and the patient advised to wait at least 15 minutes before re-insertion.

4.4 Special warnings and precautions for use

For topical use only. Not for injection.

In the elderly and others where increased intra-ocular pressure may be encountered, mydriatics and cycloplegics should be used cautiously. To avoid inducing angle-closure glaucoma, an estimation of the depth of the angle of the anterior chamber should be made.

This preparation may cause CNS disturbances which may be dangerous in infants and children. The possibility of occurrence of psychotic reaction and behavioural disturbance due to hypersensitivity to anticholinergic drugs should be borne in mind.

Extreme caution is advised for use in children and individuals susceptible to belladonna alkaloids because of the increased risk of systemic toxicity. Parents should be warned of the oral toxicity of this preparation for children and advised to wash their own hands and the child's hands following administration.

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 one minute after instillation of the drops.

4.5 Interaction with other medicinal products and other forms of interaction

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

4.6 Pregnancy and lactation

There is no evidence as to drug safety in human pregnancy and lactation nor is there evidence from animal work that it is free from hazard. This product should be used during pregnancy only when it is considered essential by a physician.

4.7 Effects on ability to drive and use machines

May cause blurred vision and sensitivity to light. Patients should be warned not to drive or engage in other hazardous activities unless vision is clear. Complete recovery from the effects of tropicamide eye drops may take up to six hours.

4.8 Undesirable effects

Local: Increased intraocular pressure, transient stinging, blurred vision and sensitivity to light secondary to pupillary dilation, photophobia with or without corneal staining. Prolonged administration may lead to local irritation, hyperaemia, oedema and conjunctivitis.

Systemic: Systemic anti-cholinergic toxicity is manifested by 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. Vomiting, giddiness and staggering may occur.

A rash may be present in children and abdominal distention in infants. Psychotic reactions, behavioural disturbances and cardio-respiratory collapse in children with this class of drug have been reported.

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 distention in infants, convulsions and hallucinations and the loss of neuro-muscular 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

Pharmacotherapeutic Group – Ophthalmologicals: Mydriatics & Cycloplegics.
ATC Code: S01F A06.

Tropicamide is an anticholinergic which blocks the responses of the sphincter muscle of the iris and the ciliary muscle to cholinergic stimulation thus dilating the pupil (mydriasis). At higher concentrations (1%), tropicamide also paralyses accommodation. This preparation acts rapidly and has a relatively short duration of action.

5.2 Pharmacokinetic properties

Tropicamide administered topically to the human eye does not bind to tissues as firmly as does atropine. The wash out time for half recovery of carbachol responsiveness was shown to be less than 15 minutes for non-pigmented iris and 30 minutes for pigmented iris.

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

Benzalkonium chloride
Disodium edetate
Sodium chloride
Sodium Hydroxide and/or
Hydrochloric acid (for pH adjustment only)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

Unopened: 3 years
Once opened: Discard 4 weeks after first opening.

6.4 Special precautions for storage

Do not store above 25°C.

Do not refrigerate or freeze.

6.5 Nature and contents of container

Pack size - 5 ml.

Drop-Tainer - Natural Low Density Polyethylene Bottle and Plug.

Polystyrene or Polypropylene cap.

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

Do not touch dropper tip to any surface as this may contaminate the contents.

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

7 MARKETING AUTHORISATION HOLDER

Alcon Laboratories (UK) Ltd.

Pentagon Park

Boundary Way

Hemel Hempstead

Hertfordshire

HP2 7UD

England

8 MARKETING AUTHORISATION NUMBER

PA 290/2/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 06 September 1988

Date of last renewal: 06 September 2008

10 DATE OF REVISION OF THE TEXT

March 2009