IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0013/102/002
Case No: 2040186

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

Novartis Pharmaceuticals UK Ltd

Frimley Business Park, **Frimley**, **Camberley**, **Surrey, GU16 7SR**, **United Kingdom**

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

TEOPTIC 2 %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 **30/08/2007**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Teoptic 2% w/v Eye Drops, Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Carteolol hydrochloride 2 % w/v.

Excipients: Benzalkonium chloride 0.005% w/v.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution
Clear, colourless solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the reduction of intraocular pressure e.g. in ocular hypertension, chronic open angle glaucoma, some secondary glaucomas.

4.2 Posology and method of administration

Adults including the elderly:
Initially one drop of 1% eye drops instilled twice daily in each affected eye. If the clinical response is not adequate the dosage may be altered to one drop of 2% eye drops twice daily in each affected eye.

Children:
Not recommended for use in children.

4.3 Contraindications

Unsatisfactorily controlled cardiac insufficiency, bronchospasm including bronchial asthma or chronic obstructive pulmonary disease, hypersensitivity to any of the components of the formulation as with all ophthalmic preparations containing benzalkonium chloride, soft contact lenses (hydrophilic lenses) should not be worn during treatment with Teoptic eye drops.

4.4 Special warnings and precautions for use

Unlike miotics, Teoptic eye drops reduce intraocular pressure without altering accommodation or pupil diameter. A slight increase in pupil diameter may be noted, however, if patients are transferred from miotic therapy to Teoptic eye drops.

4.5 Interaction with other medicinal products and other forms of interaction

As with other topically applied ophthalmic preparations Teoptic eye drops may be absorbed systemically. Teoptic eye

drops should therefore be used with caution in patients receiving systemic beta-adrenergic-receptor blocking therapy and in patients with known contra-indications to systemic beta-blockers, e.g. sinus bradycardia, second and third degree atrio-ventricular block, cardiogenic shock, right ventricular insufficiency due to pulmonary hypertension and congestive heart failure, unsatisfactorily controlled diabetes mellitus.

Teoptic eye drops may, if necessary be used in association with pilocarpine, adrenaline, carbachol and carbonic anhydrase inhibitors.

4.6 Pregnancy and lactation

Teoptic eye drops have not been studied in human pregnancy and lactation. Use during pregnancy is therefore contraindicated. In animal studies, orally administered carteolol has been shown to penetrate the breast milk and the use of Teoptic eye drops in lactating mothers should therefore be at the discretion of the physician.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Local ocular reactions such as irritation, burning, itching and pain, blurred vision, photophobia, xerosis, conjunctival hyperaemia, conjunctival discharge and corneal disorders such as diffuse superficial keratitis may occasionally develop. As with all beta-blocking agents, bradycardia, bronchospasm, rashes, dyspnoea, headache, lassitude and vertigo have occasionally been reported.

4.9 Overdose

There is no experience of overdosage with Teoptic eye drops. However, potential symptoms (typical of beta-blocking agents) which may occur after accidental oral ingestion include bradycardia, severe hypotension, acute cardiac failure, bronchospasm, hypoglycaemia, delirium and unconsciousness. Initially treatment should be by removal of any unabsorbed drug (e.g. gastric lavage) and general supportive measures, i.e. marked bradycardia should be treated in the first instance by intravenous atropine sulphate at a dose of 0.5 - 2.0 mg depending on severity; intravenous glucagon and cardiac pacemakers may be required in more severe cases; bronchospasm should be treated with appropriate bronchodilators, including beta$_2$-agonists and aminophylline where necessary. Patients should be monitored for several days as the beta-blocking effects of Teoptic may exceed its plasma half-life.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Carteolol hydrochloride is a beta-adrenergic receptor blocking agent with intrinsic sympathomimetic activity. It has no local anaesthetic effect.

5.2 Pharmacokinetic properties

The distribution of radioactivity was studied in New Zealand white rabbits after the instillation in one eye of 14C carteolol hydrochloride. The maximum levels of radioactivity were recorded on the ocular tissues and in the plasma 30 minutes to 1 hour after instillation and then declined rapidly. The highest concentrations were found in the cornea, iris, anterior sclera, ciliary body, conjunctiva, nictitating membrane and extraocular muscle. Moderate concentrations were found in the aqueous humor, posterior sclera, retina, choroid and optic nerve. Low concentrations in the lens, vitreous humor and plasma.

The concentrations of radioactivity varied dose-dependently and the elimination rate from each tissue was similar. 8 hours after instillation the levels in all tissues had fallen to 5-10% of the maximum tissue concentrations.

In the tissues of the untreated eyes, the concentrations of radioactivity were generally less than 10% of those in the treated eyes. Most of the radioactivity in the aqueous humor of the treated eyes was due to unchanged carteolol whereas that in the aqueous humor of the untreated eyes and in the plasma was due predominantly to its metabolites.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Benzalkonium chloride
Sodium dihydrogen phosphate dihydrate
Disodium phosphate dodecahydrate
Water for injections

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

Unopened : 2 years.
Opened : 28 days.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

1 x 5 ml polyethylene dropper bottle.
3 x 5 ml polyethylene dropper bottle.

Not all pack sizes may be marketed.

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

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Novartis Pharmaceuticals UK Ltd
Frimley Business Park
Frimley
Camberley
Surrey GU16 7SR
UK

8 MARKETING AUTHORISATION NUMBER

PA 13/102/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27 January 1988

Date of last renewal: 17 December 2006

10 DATE OF REVISION OF THE TEXT

March 2007