IRISH MEDICINES BOARD ACT 1995, as amended

Medicinal Products (Control of Placing on the Market) Regulations, 2007, as amended

PA0013/104/001
Case No: 2076811

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

Oculotect 50mg/ml, eye drops solution, in multi-dose containers

the particulars of which are set out in 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 **04/08/2010**.

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

Oculotect 50mg/ml, eye drops solution, in multi-dose containers.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains 50 mg povidone K25.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution.

Slightly yellowish, clear aqueous solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Symptomatic treatment of dry eyes.

4.2 Posology and method of administration

One drop into the conjunctival sac of the eye 4 times daily, or as required, depending upon the severity of the condition.

Oculotect eye drops contain a sterile solution until the original closure is broken. The tip of the container should not come into contact with any surface including the eye, as this may cause injury to the eye and contaminate the solution.

4.3 Contraindications

Hypersensitivity to any of the components of the product (e.g. preservative).

4.4 Special warnings and precautions for use

If irritation of the dry eye persists or worsens, treatment should be discontinued and the patient should consult the physician/ ophthalmologist.

Oculotect eye drops contain benzalkonium chloride as a preservative. Benzalkonium chloride may cause eye irritation and is known to discolour soft contact lenses. Therefore avoid contact with soft contact lenses. Remove contact lenses prior to application and wait at least 30 minutes before reinsertion.

4.5 Interaction with other medicinal products and other forms of interaction

If the patient instils other medication(s) into the eyes (e.g. for the treatment of glaucoma), there must be an interval of at least 5 minutes between medications. Oculotect should always be instilled last.

4.6 Pregnancy and lactation

Pregnancy:
There are no data from the use of povidone in pregnant women. Systemic exposure via ocular administration is likely to be negligible.

Animal studies are insufficient with respect to reproductive toxicity. The use of Oculotect eye drops may be considered during pregnancy, if necessary.

Lactation:
It is unknown whether povidone is excreted in human milk. However, no effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman is negligible. Ocular eye drops can be used during breast-feeding.

4.7 Effects on ability to drive and use machines

In the event of blurring of vision, patients must refrain from driving vehicles or operating machinery.

4.8 Undesirable effects

Adverse reactions are ranked under heading of frequency, 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).

The following adverse events have been reported:

- Immune system disorders
  Very rare: Irritation or hypersensitivity reactions

- Eye disorders
  Common: Mild transient burning or sticky sensation
  Not known: Blurred vision

4.9 Overdose

No case of overdose has been reported.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Ophtalmologicals, artificial tears and other products, ATC code: S01XA20.

The product does not contain any active pharmacological compounds. Due to their physical properties, non-irritant water soluble polymers can be used for moistening and lubrication of the ocular surface.

5.2 Pharmacokinetic properties

Orally administered povidone with a molecular weight of 12,600 is rapidly excreted in the urine, with the major part being excreted within 11 hours.

Following intravenous administration, long-term accumulation of povidone can be avoided by reducing the proportion of povidone of molecular weight higher than 25,000. On account of the relatively large size of the povidone molecule, penetration through the cornea is unlikely.

5.3 Preclinical safety data

No toxic effects were observed during or after two years' administration of 5 and 10% PVP K25 (povidone) in the feed of rats. No data on mutagenicity or teratogenicity are available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride
Boric acid
Calcium chloride
Potassium chloride
Magnesium chloride
Sodium chloride
Sodium lactate
Sodium hydroxide for pH adjustment
Water for injections

6.2 Incompatibilities

High salt concentrations, e.g. of sodium sulphate in cold and of sodium chloride in warm conditions, can result in precipitation of povidone. Depending on the ionic strength of the solution, methyl- and propylhydroxybenzoates easily form complexes with povidone.

6.3 Shelf Life

Unopened container: 2 years.

After opening: 4 weeks.

6.4 Special precautions for storage

Do not store above 25°C.

Keep container in the outer carton in order to protect from light.

6.5 Nature and contents of container

The container is a transparent PP -bottle with a transparent PP -dropper and a white HDPE screw cap with an integrated safety ring. One bottle contains 10 ml of the solution.

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

The content of the package will remain sterile until the original closure is broken. Any contents remaining 4 weeks after opening should be discarded.

7 MARKETING AUTHORISATION HOLDER

Novartis Pharmaceuticals UK Limited
Frimley Business Park
Frimley
Camberley
Surrey GU16 7SR
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 0013/104/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 2nd June 1998

Date of last renewal: 2nd September 2006

10 DATE OF REVISION OF THE TEXT

August 2010