**IRISH MEDICINES BOARD ACTS 1995 AND 2006**

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

**(S.I. No.540 of 2007)**

**PA0282/059/002**
Case No: 2061679

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

**Norton Healthcare Limited T/A IVAX Pharmaceuticals UK**

**Regent House, 5-7 Broadhurst Gardens**, **Swiss Cottages**, **London NW6 3RZ**, **United Kingdom**

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

**Sodium Cromoglicate 2% w/v Eye Drops**

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 **19/02/2009**.

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

Sodium Cromoglicate 2% w/v Eye Drops

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1ml contains Sodium Cromoglicate 2% w/v.

Excipients: also includes benzalkonium chloride solution 0.01% w/v.

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Eye drops, solution (Eye Drops).
A clear colourless sterile eye drops solution.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

For the relief and treatment of acute allergic conjunctivitis such as hay fever, chronic allergic conjunctivitis and vernal keratoconjunctivitis. Sodium cromoglicate inhibits the release from the sensitised mast cells of mediators of the allergic reaction.

### 4.2 Posology and method of administration

Topical application to the eye up to 4 times daily.

Recommended Dosage Schedules:
Adults: One to two drops into each affected eye up to four times daily.
Elderly: As adults.
Children: As adults.
Infants and neonates: Not recommended.
Special groups: No special recommendations.

### 4.3 Contraindications

No special contraindications except known hypersensitivity to sodium cromoglicate **or any of the excipients.**

### 4.4 Special warnings and precautions for use

Since Sodium Cromoglicate therapy is prophylactic in nature, it is important to continue therapy in those patients who benefit.

Do not administer parenterally. Do not wear soft contact lenses during treatment.

If sodium cromoglicate eye drops are added to existing sodium cromoglicate or steroid controlled asthma therapy, the prophylactic effects of sodium cromoglicate may be exaggerated.

## 4.5 Interaction with other medicinal products and other forms of interaction

None.

## 4.6 Pregnancy and lactation

No embryopathic effects have been recorded with this drug. No data is available on the secretion of sodium cromoglicate in breast milk. Use during pregnancy should only be considered if the potential benefit outweighs the risk.

## 4.7 Effects on ability to drive and use machines

This preparation may cause transient blurring of vision, following instillation. Do not drive or operate machinery until clarity of vision is restored.

## 4.8 Undesirable effects

As with other ophthalmic preparations, transient blurring of vision may occur.

Since the introduction of sodium cromoglicate no pharmacogenetic problems or side effects have been reported. No long-term harm has resulted from clinical trials on its use and any reported side effects have ceased as soon as it has stopped.

## 4.9 Overdose

Sodium cromoglicate is poorly absorbed through the gastro-intestinal tract. In cases of overdose, no action other than medical observation should be required.

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

Sodium cromoglicate has no bronchodilator, antihistaminic and no anti-inflammatory activity. The exact mechanism of action is still not fully understood but it is known to be purely prophylactic. *In-vitro* and *in-vivo* studies have consistently suggested that sodium cromoglicate inhibits the release of inflammatory mediators from sensitised mast cells. It appears to inhibit reactions caused by both antigenic and non-antigenic stimuli and prevents both the immediate (Type I) and late (Type II) asthmatic responses. Most evidence suggests that the effects of sodium cromoglicate are due to stabilisation of mast cell-membranes although the precise mechanism of action remains unknown.

## 5.2 Pharmacokinetic properties

Due to lipid insolubility, sodium cromoglicate is effective only by topical administration. Only very low concentrations are systematically absorbed in man (0.03%). A systematically absorbed drug is rapidly excreted unchanged in the bile and urine.

## 5.3 Preclinical safety data

Not applicable.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Benzalkonium chloride solution
Disodium edetate
Purified water

### 6.2 Incompatibilities

No incompatibilities are anticipated with the proposed usage of the product.

### 6.3 Shelf Life

Unopened: 3 years
Opened: 28 days

### 6.4 Special precautions for storage

Do not store above 25°C.
Keep the container in the outer carton.

### 6.5 Nature and contents of container

15 ml capacity polyethylene eyedropper bottles containing 13.5ml or 10ml of eye drop solution, blow moulded as part of the filling process, the eyedropper being sealed from the atmosphere. The bottle is capped with a high density polyethylene cap that has an internal spike which, when the cap is tightened, breaks the seal of the dropper. The individual bottles are packed in cardboard cartons.

### 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

Norton Healthcare Ltd
T/A IVAX Pharmaceuticals UK
Regent House
5-7 Broadhurst Gardens
Swiss Cottage
London, NW6 3RZ
United Kingdom

## 8 MARKETING AUTHORISATION NUMBER

PA 282/59/2

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24 of February 1992

Date of last renewal: 24 February 2007

## 10 DATE OF REVISION OF THE TEXT

February 2009