

**IRISH MEDICINES BOARD ACTS 1995 AND 2006**

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

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

**PPA1151/120/001**

Case No: 2066396

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

**Imbat Limited**

**Unit L2, North Ring Business Park, Santry, Dublin 9**

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

**Hay-Crom 2% w/v Aqueous 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 **05/03/2010**.

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

Hay-Crom 2% w/v Aqueous Eye Drops, Solution

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium Cromoglicate 2.00% w/v

Excipient:

Benzalkonium chloride 0.01% w/v

For full list of excipients, see section 6.1

#### 3 PHARMACEUTICAL FORM

Eye drops, solution

*Product imported from the UK:*

Clear, pale, straw coloured solution supplied in a dropper bottle.

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

For the prophylaxis and symptomatic treatment of acute and chronic allergic conjunctivitis and seasonal kerato-conjunctivitis.

##### 4.2 Posology and method of administration

###### Adults (including the elderly) and children

One or two drops into each affected eye up to 4 times daily.

###### Route of Administration

Topical instillation into conjunctival sac.

Your eye drops are provided in a sealed bottle.

To prepare your eye drops for use: the large white cap should be fully screwed down in a clockwise direction.

During use, remove only the blue nozzle cap and always replace after use.

###### Do not remove the white cap during use

- To use: place one or two drops into each affected eye, up to four times daily, or as instructed by your doctor. This applies to adults and children.
- Preferably using a mirror, pull the lower eye-lid gently forward and holding the dropper bottle upside down and without touching the eye (gentle pressure may be applied to the bottle). Then blink a few times to disperse the eye drops.
- If you forget to instill the eye drops, use the recommended number of drops as soon as you remember, then continue as normal.

### 4.3 Contraindications

Use in patients hypersensitive to the active ingredient.

Use in patients hypersensitive to benzalkonium chloride.

Use in patients hypersensitive to disodium edetate.

### 4.4 Special warnings and precautions for use

Side effects include transient blurred vision and local stinging sensation.

Do not drive or operate machinery until clarity of vision is restored.

Any preparation remaining four weeks after opening the container should be discarded.

Since the treatment is primarily protective it should be continued as directed.

Soft contact lenses should not be worn during period of use of this preparation.

Not for injection. Do not use if the pack is open when supplied or if any cloudiness is evident.

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

Not known.

### 4.6 Pregnancy and lactation

As with all medication, caution should be exercised, especially during the first trimester of pregnancy. Cumulative experience suggests that sodium cromoglicate has no embryotoxic effects. It should be used in pregnancy only where there is a clear need.

It is not known whether sodium cromoglicate is excreted into human breast milk, but on the basis of its physio-chemical properties, this is considered unlikely.

### 4.7 Effects on ability to drive and use machines

These drops cause transient blurred vision, do not operate machinery until clarity of vision is restored.

### 4.8 Undesirable effects

Side effects include transient blurred vision and local stinging sensation.

### 4.9 Overdose

If the eye drops are ingested:

Sodium cromoglicate is poorly absorbed through the gastro-intestinal tract. In case of overdosage, no action other than medical observation should be necessary.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

A mast cell stabiliser preventing the release of granules that produce the allergen-mediated inflammatory reaction in the eye with negligible systemic adsorption from the eye.

### 5.2 Pharmacokinetic properties

See above.

### 5.3 Preclinical safety data

Not Applicable.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Disodium edetate  
Benzalkonium chloride  
Purified water

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf Life

The shelf life expiry date of this product is the date shown on the bottle label and outer carton of the product as marketed in the country of origin

The product should not be used later than 28 days after first opening.

### 6.4 Special precautions for storage

Do not store above 30°C. Keep bottle in the outer carton to protect from light.

### 6.5 Nature and contents of container

1 clear plastic eye dropper bottle containing 13.5ml of solution in an overlabelled outer carton.

### 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 Parallel Product Authorisation Holder

Imbat Limited  
Unit L2  
North Ring Business Park  
Santry  
Dublin 9

**8 Parallel Product Authorisation Number**

PPA1151/120/001

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

Date of first authorisation: 5th March 2010

**10 DATE OF REVISION OF THE TEXT**