

**SODIUM CROMOGLICATE 2% W/V EYE DROPS**

**PL 10622/0231**

**PL 10622/0237**

**UKPAR**

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## **SODIUM CROMOGLICATE 2% W/V EYE DROPS**

**PL 10622/0231**

**PL 10622/0237**

### **LAY SUMMARY**

The Medicines and Healthcare products Regulatory Agency (MHRA) granted PLIVA Pharma Ltd two Marketing Authorisations (licences) for the medicinal product Sodium Cromoglicate 2% w/v Eye Drops (Product Licence numbers: 10622/0231 and 10622/0237). This product is available from pharmacies without a prescription, under the supervision of a pharmacist.

Sodium Cromoglicate 2% w/v Eye Drops contain the active ingredient sodium cromoglicate and are used to relieve hayfever symptoms in the eyes. It is thought that sodium cromoglicate works by reducing the allergic responses that lead to red, itchy, watery and puffy eyes in some hayfever sufferers.

No new or unexpected safety concerns arose from these simple applications and it was, therefore, judged that the benefits of taking Sodium Cromoglicate 2% w/v Eye Drops outweigh the risks, hence Marketing Authorisations have been granted.

# **SODIUM CROMOGLICATE 2% W/V EYE DROPS**

**PL 10622/0231**

**PL 10622/0237**

## **SCIENTIFIC DISCUSSION**

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## **INTRODUCTION**

The UK granted marketing authorisations for the medicinal product Sodium Cromoglicate 2% w/v Eye Drops (PLs 10622/0231 and 10622/0237) to PLIVA Pharma Ltd on 19 January 2007. This product has a P status and is available to the general public without prescription.

These applications were submitted as simple abridged informed consent applications, according to Article 10c of EC Directive 2001/83. The cross reference product is Pliva Sodium Cromoglicate Eye Drops 2%w/v (PL 10622/0016) granted to PLIVA Pharma Ltd on 23 November 1994.

No new data were submitted, nor was it necessary for these simple applications as the data are identical to those of the previously granted cross-reference product. As the cross-reference product was granted prior to the introduction of current legislation, no Public Assessment Report (PAR) was generated for it.

# **PHARMACEUTICAL ASSESSMENT REPORT**

## **1 Introduction**

### **1.1 Legal Basis**

These are two simple abridged applications for Sodium Cromoglicate 2% w/v eye drops, with legal status P. The applicant claims essential similarity, under Article 10c, to Pliva Sodium Cromoglicate Eye Drops 2% w/v (PL 10622/0016) held by the applicant and granted 23 November 1994.

### **1.2 Legal Status**

The active, sodium cromoglicate, has a legal status of P if sold as eye drops in a quantity of no more than 10ml.

### **1.3 Letters of Access**

A letter of access, dated 24 March 2004, has been provided that refers to the DMF submitted in support of the application.

A letter of consent, dated 16 April 2004, from the applicant, who holds the MA for the reference product, has been provided and is acceptable. Confirmation that the manufacturers are prepared to manufacture the product on the applicant's behalf has been provided. Written confirmation that the applicant has access to all the data supporting the application and that Part II of the data is in their possession has been provided.

## **2 Expert Reports**

The expert statements provided by the quality, non-clinical and clinical experts are satisfactory. The statements confirm that the experts have performed the duties set out in Article 2 of Council Directive 75/319/EEC, in accordance with Part IC of annex to Council Directive 75/318/EEC. The expert statements are signed. The CVs of the experts are acceptable.

## **3 Part I**

### **3.1 Product Name and Appearance**

The product name is considered acceptable.

### **3.2 Summary of Product Characteristics**

The Summary of Product Characteristics for this product is satisfactory.

### **3.3 Patient Information leaflet**

A text version of the patient information leaflet has been provided. The PIL is in line with the SPC and is satisfactory.

### **3.4 Label**

All labelling for this product is satisfactory.

### **3.5 MAA Form**

The sites of assembly, distribution and storage are in line with the reference product. This is accepted. The active manufacturing site is in line with the reference product.

### **3.6 TSE**

Section 2.6.2 of the MAA form states that none of the ingredients are of animal origin. This is in line with the reference product.

### 3.7 Part IC: Additional Data Requirements

The Finished Product Specification and manufacturing process are in line with the reference product and Mail 109.

## **4 Conclusion**

Product licenses may be granted for this product.

## **PRECLINICAL ASSESSMENT**

No new preclinical data have been supplied with these applications and none are required for applications of this type.

## **CLINICAL ASSESSMENT**

No new clinical data have been supplied with these applications and none are required for applications of this type.



## **OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT**

### **QUALITY**

The data for these applications are consistent with that previously assessed for the cross-reference product and as such has been judged to be satisfactory.

### **PRECLINICAL**

No new preclinical data were submitted and none are required for applications of this type.

### **EFFICACY AND SAFETY**

The efficacy of sodium cromoglicate has been well documented in the past. No new or unexpected safety concerns arise from these applications.

The SPC, PIL and labelling are satisfactory.

### **RISK BENEFIT ASSESSMENT**

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant's product is identical to the cross-reference product. The risk benefit ratio is considered to be positive.

## **SODIUM CROMOGLICATE 2% W/V EYE DROPS**

**PL 10622/0231**

**PL 10622/0237**

### **STEPS TAKEN FOR ASSESSMENT**

<b>1</b>	The MHRA received the marketing authorisation application on 2 June 2004
<b>2</b>	Following assessment of the application the MHRA requested further information relating to the quality dossier on 2 March 2006
<b>3</b>	The applicant responded to the MHRA's requests, providing further information on 7 November 2006
<b>4</b>	Following assessment of the response the MHRA requested further information relating to the quality dossier on 7 November 2006
<b>5</b>	The applicant responded to the MHRA's requests, providing further information on 26 November 2006
<b>6</b>	The application was determined on 24 January 2007

## SUMMARY OF PRODUCT CHARACTERISTICS

**PL 10622/0231:**

**1 NAME OF THE MEDICINAL PRODUCT**

Sodium Cromoglicate 2% w/v Eye Drops

**2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Sodium cromoglicate (equivalent to 20.0 mg/ml anhydrous sodium cromoglicate).

For excipients, see 6.1

**3 PHARMACEUTICAL FORM**

Eye drops

Sodium Cromoglicate 2% w/v Eye Drops are a clear solution.

**4 CLINICAL PARTICULARS**

4.1 Therapeutic indications

For the treatment of Hayfever

4.2 Posology and method of administration

Adults and Children:

One or two drops to be administered into each eye four times daily, or as prescribed by the doctor.

Elderly:

There is no evidence to suggest that dosage alteration is required for elderly patients.

4.3 Contraindications

Known hypersensitivity to any ingredient, including sodium cromoglicate, benzalkonium chloride and disodium edetate.

4.4 Special warnings and precautions for use

Soft contact lenses should not be worn during treatment with Sodium Cromoglicate Eye Drops.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

#### 4.6 Pregnancy and lactation

Cumulative experience with sodium cromoglicate suggests that it has no adverse effects on foetal development. However, as with all medicines, caution should be exercised during pregnancy, and it should be used in pregnancy only when there is a clear need.

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

Instillation may cause transient blurring of vision. Do not drive or operate machinery if affected.

#### 4.8 Undesirable effects

Transient stinging and blurring of vision may occur. Other symptoms of local irritation have been reported rarely.

#### 4.9 Overdose

Overdosage is very unlikely. In the event of accidental ingestion, symptomatic treatment is recommended.

### **5 PHARMACOLOGICAL PROPERTIES**

#### 5.1 Pharmacodynamic properties

**Pharmacotherapeutic group:** Other antiallergics

**ATC-code:** S01G X01

The solution exerts its effect locally in the eye.

Sodium cromoglicate inhibits the release from sensitised mast cells of mediators of the allergic reaction.

#### 5.2 Pharmacokinetic properties

Limited systemic absorption may be expected via the ocular mucosa.

Sodium cromoglicate is not metabolised.

#### 5.3 Preclinical safety data

None stated.

### **6 PHARMACEUTICAL PARTICULARS**

#### 6.1 List of excipients

Disodium edetate

Benzalkonium chloride

Water

6.2 Incompatibilities

None known

6.3 Shelf life

24 months unopened – 28 days opened.

6.4 Special precautions for storage

Store below 25°C, protected from direct sunlight.

6.5 Nature and contents of container

White polyethylene bottles fitted with integral dropper and closed with a polypropylene or polyethylene screw cap containing 5 or 10ml eye drops.

6.6 Special precautions for disposal

None stated.

**7 MARKETING AUTHORISATION HOLDER**

PLIVA Pharma Ltd.

Vision House

Bedford Road

Petersfield

Hampshire

GU32 3QB

**8 MARKETING AUTHORISATION NUMBER(S)**

PL 10622/0231

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

19/01/2007

**10 DATE OF REVISION OF THE TEXT**

19/01/2007

**PL 10622/0237:**

**1 NAME OF THE MEDICINAL PRODUCT**

Sodium Cromoglicate 2% w/v Eye Drops

**2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Sodium cromoglicate (equivalent to 20.0 mg/ml anhydrous sodium cromoglicate).

For excipients, see 6.1

### **3 PHARMACEUTICAL FORM**

Eye drops

Sodium Cromoglicate 2% w/v Eye Drops are a clear solution.

### **4 CLINICAL PARTICULARS**

#### 4.1 Therapeutic indications

For the treatment of Hayfever

#### 4.2 Posology and method of administration

Adults and Children:

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Elderly:

There is no evidence to suggest that dosage alteration is required for elderly patients.

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None known.

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Cumulative experience with sodium cromoglicate suggests that it has no adverse effects on foetal development. However, as with all medicines, caution should be exercised during pregnancy, and it should be used in pregnancy only when there is a clear need.

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Instillation may cause transient blurring of vision. Do not drive or operate machinery if affected.

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Vision House

Bedford Road  
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Hampshire  
GU32 3QB

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PL 10622/0237

**9**     **DATE OF FIRST AUTHORISATION/RENEWAL OF THE     AUTHORISATION**  
19/01/2007

**10**    **DATE OF REVISION OF THE TEXT**  
19/01/2007



## PATIENT INFORMATION LEAFLET

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

Please read all of this leaflet carefully before you used Sodium Cromoglicate Eye Drops.

#### **Product Name**

Sodium Cromoglicate 2% w/v Eye Drops

#### **What is in your drops?**

The active ingredient is sodium cromoglicate 2% w/v.

The other ingredients are disodium edetate, benzalkonium chloride and water. It comes in packs containing 5ml or 10ml of drops.

#### **How do your drops work?**

The active ingredient of Sodium Cromoglicate Eye Drops has an anti-inflammatory action in eyes affected by allergic conditions like hayfever. This means it reduces redness, soreness and itching when used regularly.

#### **Who provides the drops?**

Sodium Cromoglycate Eye Drops are made by Alcon Cusi SA, 08320 El Masnou, Barcelona, Spain. The product licence holder is: PLIVA Pharma Ltd., Vision House, Bedford Road, Petersfield, Hampshire, GU32 3QB.

#### **What are Sodium Cromoglicate Drops for?**

Sodium Cromoglicate Eye Drops are for the treatment and relief of soreness, redness and itching of the eyes due to seasonal allergies such as hayfever.

#### **Before you use Sodium Cromoglicate Eye Drops**

Ask yourself the following questions:

- Do you wear soft contact lenses?
- Are you sensitive to eye drops containing sodium cromoglicate, benzalkonium chloride or any of the ingredients listed above?
- Are you pregnant or breast feeding?

If the answer to any of these questions is yes, do not use the drops until you have discussed it with your doctor or pharmacist.

This product contains benzalkonium chloride. This may cause eye irritation. Avoid contact with soft contact lenses. Remove contact lenses prior to application and wait at least 15 minutes before reinsertation. Benzalkonium chloride is known to discolour soft contact lenses.

If you have any questions concerning the use of these eye drops in a child, or are unsure whether the child has allergic eyes, you should seek advice from your doctor or pharmacist.

- Sodium Cromoglicate Eye Drops can cause blurred vision for a few minutes after use. If this happens, do not operate machinery until the blurring stops.

**How do I use Sodium Cromoglicate Eye Drops?**

For external use only.

Adults (including the elderly) and children: Place one or two drops into each eye 4 times daily, or as directed by your doctor.

Wash your hands before using the drops. Tilt your head back and carefully pull down your lower eyelid. Without touching the eyelid with the tip of the dropper, put 1 or 2 drops into your lower lid and then blink a few times to make sure your whole eye is covered by the liquid. Replace the cap on the bottle.

It is important to use Sodium Cromoglicate Eye Drops regularly every day to keep your eye condition controlled.

If you forget to use the drops, use them as soon as you remember.

**What might happen when I use Sodium Cromoglicate Eye Drops?**

Your eyes might sting a little just after you use the drops. If they sting badly, or if your eyes get worse, stop using the drops and tell your doctor or pharmacist.

If anything else happens, tell your doctor or pharmacist.

**Looking after your Sodium Cromoglicate Eye Drops**

Do not use the eye drops after the expiry date printed on the label.

Do not use the eye drops more than four weeks after first opening the bottle.

Do not store the eye drops above 25°C. Keep them in the original container and out of direct sunlight.

**Remember: Keep all medicines out of the reach and sight of children.**

Date of last revision: May 2005



## LABELLING

**PL 10622/0231:**

Label

<p><b>Sodium Cromoglicate</b> <b>2% w/v Eye Drops</b>      10ml</p> <p>Active ingredient: Sodium Cromoglicate. Also contains benzalkonium chloride, disodium edetate, water. <b>FOR EXTERNAL USE ONLY</b> <b>PLEASE READ THE ACCOMPANYING LEAFLET</b> Do not use after date shown on pack. Discard four weeks after opening. Do not store above 25°C. Keep out of direct sunlight. <b>KEEP OUT OF THE REACH AND SIGHT OF CHILDREN</b> MA Holder: PLIVA Pharma Ltd, Vision House, Bedford Road, Petersfield, Hampshire, GU32 3QB, PL 10622/0231</p>	
	<p>Lot no: Use by:</p>
	

Carton





<p>Expiry: Lot No:</p>	<p><b>Sodium Cromoglicate</b> <b>2% w/v Eye Drops</b> 10ml For the treatment of eye symptoms of hayfever</p> 	<p><b>Sodium Cromoglicate</b> <b>2% w/v Eye Drops</b></p> 
<p><b>Sodium Cromoglicate 2% w/v</b> <b>Eye Drops</b> 10ml</p> <p><b>FOR EXTERNAL USE ONLY</b></p> 		
<p><b>DIRECTIONS</b> Check that the cap seal is not broken before first use Adults and children: Gently squeeze 1 or 2 drops into each eye, 4 times a day. If symptoms persist, consult your doctor. <b>DO NOT EXCEED THE STATED DOSE</b> MA Holder: PLIVA Pharma Ltd, Vision House, Bedford Road, Petersfield, Hampshire GU32 3QB, PL 10622/0231</p> <p><b>P</b></p>		
<p>Do not use when wearing soft contact lenses. Consult your doctor before using this product if you are pregnant or breastfeeding. Do not use after date shown on pack. Discard four weeks after opening Do not store above 25°C. Keep out of direct sunlight. <b>KEEP OUT OF THE REACH AND SIGHT OF CHILDREN</b> Active ingredient: Sodium Cromoglicate. Also contains benzalkonium chloride, disodium edetate and water.</p> <p><b>BAR CODE</b></p>		

**PL 10622/0237:**

Label

<p><b>Sodium Cromoglicate</b> <b>2% w/v Eye Drops</b>      10ml</p> <p>Active ingredient: Sodium Cromoglicate. Also contains benzalkonium chloride, disodium edetate, water.</p> <p><b>FOR EXTERNAL USE ONLY</b> <b>PLEASE READ THE ACCOMPANYING LEAFLET</b></p> <p>Do not use after date shown on pack. Discard four weeks after opening. Do not store above 25°C. Keep out of direct sunlight. <b>KEEP OUT OF THE REACH AND SIGHT OF CHILDREN</b></p> <p>MA Holder: PLIVA Pharma Ltd, Vision House, Bedford Road, Petersfield, Hampshire, GU32 3QB, PL 10622/0237</p>	 <p>Lot no:</p> <p>Use by:</p> 
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Carton

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