1 NAME OF THE MEDICINAL PRODUCT

Allercrom 2% w/v Eye Drops
Mylan Allercrom 2% w/v Eye Drops
Murine Hayfever Relief 2% w/v Eye Drops

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

QUALITATIVE AND QUANTITATIVE COMPOSITION Sodium Cromoglicate (equivalent to 20.0 mg/ml anhydrous Sodium Cromoglicate).
[Sodium Cromoglicate 2.0% w/v]

For a full list of 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 relief and treatment of the eye symptoms of hayfever.

4.2 Posology and method of administration

Allercrom Eye Drops should not be used continuously for more than 14 days except on the advice of a doctor or pharmacist.

Adults and Children over 6 years:
One or two drops to be administered into each eye four times daily.

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

This formulation of Sodium Cromoglicate Eye Drops contains benzalkonium chloride as a preservative. Benzalkonium chloride may be deposited in soft contact lenses. Hence, soft contact lenses should not be worn during treatment with sodium cromoglicate eye drops. Other types of contact lenses should be removed before instillation of the drops and not reinserted earlier than 15 minutes after use.

Patients should also be instructed that ocular solutions, if handled improperly can become contaminated by common bacteria known to cause ocular infections.

Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions. Patients should also be advised that if they develop any intercurrent ocular condition (e.g. trauma, ocular surgery or infection), they should immediately seek their physician's advice concerning the continued use of present multi-dose container. There have been reports of bacterial keratitis associated with the use of topical ophthalmic products.

The carton label and patient information leaflet will state:

- the patient should consult a doctor or pharmacist if symptoms do not start to improve within 48 hours.

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.

It is not known whether sodium cromoglicate is excreted in breast milk but on the basis of its physico-chemical properties, this is considered unlikely. There is no information to suggest the use of sodium cromoglicate has any undesirable effects on the baby.

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

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

Benzalkonium chloride
Disodium edetate
Sodium Chloride
Polysorbate 80
Water for Injection

6.2 Incompatibilities
None known.

6.3 Shelf life
24 months unopened. 1 month opened.

6.4 Special precautions for storage
Do not store above 30 ^{O}C, protected from direct sunlight.
To avoid contamination do not touch dropper tip to any surface.

6.5 Nature and contents of container
Low Density Polyethylene BFS bottles with a polystyrene spiked cap which contains 5 ml and 10 ml of Sodium Cromoglicate 2 % w/v Eye Drops solution.

6.6 Special precautions for disposal
None stated.

7 MARKETING AUTHORISATION HOLDER

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Fareham, Hampshire PO15 7FE

8 MARKETING AUTHORISATION NUMBER(S)

PL 15872/0008

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

16/05/2007

10 DATE OF REVISION OF THE TEXT

15 November 2012