Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Tilavist Eyedrops Solution 2.0% w/v

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Nedocromil sodium: 2.0% w/v.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution
Clear yellow solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Tilavist is indicated for the prevention and treatment of allergic conjunctivitis, including seasonal allergic conjunctivitis, perennial allergic conjunctivitis and vernal kerato-conjunctivitis.

4.2 Posology and method of administration

For ocular use.

Adults (including the elderly) and children aged 6 years and over:

In seasonal allergic conjunctivitis: one drop into each eye twice daily increasing when necessary to four times daily.

In perennial allergic conjunctivitis and vernal kerato-conjunctivitis: one drop into each eye four times daily.

Tilavist should be used regularly to ensure optimum control of symptoms. There is only limited clinical trial experience with Tilavist in children aged 3 to 6 years. Therefore use in this age range cannot be recommended.

4.3 Contraindications

Tilavist is contraindicated in patients with known hypersensitivity to nedocromil sodium, benzalkonium chloride or other constituents of the formulation.

Tilavist should not be used in patients while wearing soft contact lenses.

4.4 Special warnings and precautions for use

In patients who continue to wear hard or gas permeable contact lenses during Tilavist treatment, the lenses should be taken out of the eye prior to instillation of the drops and not inserted again for at least 15 minutes.

4.5 Interaction with other medicinal products and other forms of interaction

None have been reported.

4.6 Pregnancy and lactation

Studies in pregnant and lactating animals have failed to reveal a hazard with Nedocromil Sodium. No recommendation can be made at present for the use of this preparation in pregnant and lactating women. As with all new medicines caution should be exercised during pregnancy (especially during the first trimester) and whilst breastfeeding.

4.7 Effects on ability to drive and use machines

Tilavist has no known effect on the ability to drive or operate machinery. Additionally, no sedative effects have been reported following the administration of Tilavist.

4.8 Undesirable effects

Transient stinging and burning may occur after instillation. Other symptoms of local irritation have been reported rarely. Some patients have reported a distinctive taste.
The following effects have also been noted: eye pain, hypersensitivity reaction (local) and gritty eye sensation.

4.9 Overdose

Animal studies have not revealed any significant toxic effects of nedocromil sodium, even at high doses. Extended human studies have not revealed any additional safety hazards.

Overdosage is therefore, unlikely to cause any serious problems. However, if overdosage is suspected treatment should be supportive and directed to the control of the relevant symptoms.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Tilavist, the 2% topical ophthalmic preparation of nedocromil sodium, displays specific anti-allergic and anti-inflammatory properties relevant to ocular allergic conditions.

Nedocromil Sodium has been shown to inhibit the activation of a range of cell types which are likely to be involved in the Type I allergic response in the conjunctiva. These include mast cells, eosinophils, neutrophils and monocytes.

Nedocromil sodium prevents the release of inflammatory mediators such as histamine, leukotrienes and cytokines from these cells and prevents the migratory response of some of these cell types, thus reducing the Type I allergic response in the conjunctiva.

5.2 Pharmacokinetic properties

Following ocular administration of Tilavist, less than 4% of the dose is absorbed following multiple dosing. Absorption occurs primarily through the nasal mucosa, as approximately 80% of the ocular dose drains into the nose via the naso-lachrymal duct; 1-2% of the dose may be absorbed orally. Nedocromil sodium is reversibly bound to plasma proteins and is not metabolised, but excreted unchanged in bile and urine. The drug is rapidly cleared from the circulation (plasma clearance 10.2 ± 1.3ml/min/kg, elimination half-life 5.3 ± 0.9 min) and accumulation does not occur with repeated dosing.

5.3 Preclinical safety data

Animal studies have failed to reveal significant toxic effects with nedocromil even at high doses.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride
Disodium edetate
Sodium chloride
Purified water

6.2 Incompatibilities

None known.
No other medicaments should be mixed with the solution.

6.3 Shelf Life

3 years unopened. Discard any remaining contents 28 days after first opening the bottle.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

Tilavist is presented in a 5ml or in a 10ml translucent low density polyethylene bottle fitted with a low density polyethylene dropper plug and a polypropylene cap.
Not all pack sizes may be marketed.

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

Fisons Limited
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50, Kings Hill Avenue
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8 MARKETING AUTHORISATION NUMBER

PA 18/50/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19 September 1995

Date of last renewal: 19 September 2005

10 DATE OF REVISION OF THE TEXT

October 2005