Opticrom™ Hayfever 2.0% w/v Eye Drops, Solution

PL 04425/0628

UKPAR

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The Medicines and Healthcare products Regulatory Agency (MHRA) granted a Marketing Authorisation (licence) for the medicinal product Opticrom™ Hayfever 2.0% w/v Eye Drops, Solution (product licence number: 04425/0628). These eye drops can only be bought from pharmacies.

Opticrom™ Hayfever 2.0% w/v Eye Drops, Solution is used for the relief of eye allergies. Signs of an allergic reaction include itchy, watery, red or inflamed eyes and puffy eyelids. These allergies can happen:
- At any time of the year, this is called perennial allergic conjunctivitis
- In different seasons of the year caused by different pollens. This is called ‘seasonal allergic conjunctivitis’ or hay fever.

Opticrom™ Hayfever 2.0% w/v Eye Drops, Solution contains an active ingredient called sodium cromoglicate, which works by stopping the release of the natural substances in your eyes that can lead to an allergic reaction.

Opticrom™ Hayfever 2.0% w/v Eye Drops, Solution raised no clinically significant safety concerns and it was, therefore, judged that the benefits of using this product outweigh the risks; hence a Marketing Authorisation has been granted.
SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the UK granted a marketing authorisation for the medicinal product Opticrom™ Hayfever 2.0% w/v Eye Drops, Solution to Aventis Pharma Ltd (trading as Sanofi-aventis) on 16 February 2009.

This is an abridged, simple application for Opticrom™ Hayfever 2.0% w/v Eye Drops, Solution submitted under Article 10(c) of EC Directive 2001/83. No new data were submitted, nor was it necessary for this simple application, as the data are identical to those of the previously granted cross-reference product. The reference product is Opticrom Allergy 2.0% w/v eyedrops, solution (PL 04425/0323), which was licensed to Aventis Pharma on 16 January 1998.

As the cross-reference product was granted prior to the introduction of current legislation, no Public Assessment Report (PAR) was generated for it.

Opticrom™ Hayfever 2.0% w/v Eye Drops are indicated for the relief and treatment of seasonal and perennial allergic conjunctivitis.
LETTERS OF ACCESS
A letter confirming that the applicant is in possession of the dossier for the reference product is provided, although this is not required as the Marketing Authorisation holder for the test and reference product is identical.

The finished product manufacturer has provided written confirmation that they are prepared to manufacture the product on the applicant’s behalf.

TSE
The applicant has declared that there are no materials of animal and/or human origin contained in, or used in the manufacturing process of, the medicinal product. This is in line with the reference product.

ADDITIONAL DATA REQUIREMENTS
The manufacturing processes, finished product specifications and active ingredient specifications are in line with the reference product and are satisfactory.

EXPERT REPORTS
Satisfactory expert reports in the form of quality, non-clinical and clinical overall summaries are provided, with signed declarations from each expert confirming that the applicant’s product is identical to the reference product in all particulars. Expert CV’s are also submitted and are acceptable.

PRODUCT LITERATURE
All product literature (SPC, PIL and labelling) is satisfactory. The package leaflet has been submitted to the MHRA along with results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC. The results indicate that the package leaflet is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.

ASSESSOR’S OVERALL CONCLUSIONS
A product licence may be granted for this product.
PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with this application and none is required for an application of this type.
CLINICAL ASSESSMENT

OVERVIEW
An appropriate clinical overview has been included in the dossier.

BIOAVAILABILITY AND BIOEQUIVALENCE
No bioequivalence study has been performed to support this application and none is needed.

PRODUCT LITERATURE
All product literature (SPC, PIL and labelling) is satisfactory. The package leaflet has been submitted to the MHRA along with results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC. The results indicate that the package leaflet is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.

ASSESSOR’S OVERALL CONCLUSIONS
It is recommended that a marketing authorisation can be granted.
OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY
The data for this application is 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
The efficacy of sodium cromoglycate is well established.

The SPC, PIL and labelling are satisfactory and consistent with the product literature for the cross-reference product.

RISK BENEFIT ASSESSMENT
The quality of the product is acceptable, no significant preclinical or clinical safety concerns were identified. The applicant’s product is identical to the cross-reference product. Extensive clinical experience with sodium cromoglycate is considered to have demonstrated the therapeutic value of the compound. The risk benefit ratio is therefore considered to be positive.
OPTICROM™ HAYFEVER 2.0% W/V EYE DROPS, SOLUTION

PL 04425/0628

**STEPS TAKEN FOR ASSESSMENT**

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<td>1</td>
<td>The MHRA received the marketing authorisation application on 14 October 2008</td>
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<td>Following standard checks and communication with the applicant the MHRA considered the application valid on 31 October 2008</td>
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<td>The application was determined on 16 February 2009</td>
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SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Opticrom™ Hayfever 2.0% w/v Eye Drops, Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Sodium cromoglicate 2.0% w/v.

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM
Eye Drops, Solution (Eye Drops)

A clear colourless or pale yellow liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
For the relief and treatment of seasonal and perennial allergic conjunctivitis.

4.2 Posology and method of administration
Topical Ophthalmic administration

One or two drops in each eye four times a day or as indicated by the doctor.

Elderly

No current evidence for alteration of the dose.

4.3 Contraindications
The product is contraindicated in patients who have shown hypersensitivity to Sodium cromoglicate, Benzalkonium chloride or Disodium edetate.

4.4 Special warnings and precautions for use
Discard any remaining contents four weeks after opening the bottle.

As with other ophthalmic solutions containing Benzalkonium chloride, soft contact lenses should not be worn during treatment period.

4.5 Interaction with other medicinal products and other forms of interaction
None known.

4.6 Pregnancy and lactation
Pregnancy
As with all medication, caution should be exercised especially during the first trimester of pregnancy. Cumulative experience with Sodium cromoglicate suggests that it has no adverse effects on foetal development. It should be used in pregnancy only where there is a clear need.

Lactation
It is not known whether Sodium cromoglicate is excreted in human breast milk but, on the basis of its physicochemical 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
As with all eye drops, instillation of these eye drops may cause a transient blurring of vision.

4.8 Undesirable effects

Eye Disorders
Transient stinging and burning may occur after instillation. Other symptoms of local irritation have been reported rarely.

4.9 Overdose
No action other than medical observation should be necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC: S01XA

*In vitro* and *in vivo* animal studies have shown that Sodium cromoglicate inhibits the degranulation of sensitised mast cells which occurs after exposure to specific antigens. Sodium cromoglicate acts by inhibiting the release of histamine and various membrane derived mediators from the mast cell.

Sodium cromoglicate has demonstrated the activity *in vitro* to inhibit the degranulation of non-sensitised rat mast cells by phospholipase A and subsequent release of chemical mediators. Sodium cromoglicate did not inhibit the enzymatic activity of released phospholipase A on its specific substrate.

Sodium cromoglicate has no intrinsic vasoconstrictor or antihistamine activity.

5.2 Pharmacokinetic properties
Sodium cromoglicate is poorly absorbed. When multiple doses of Sodium cromoglicate ophthalmic solution are instilled into normal rabbit eyes, less than 0.07% of the administered dose of Sodium cromoglicate is absorbed into the systemic circulation (presumably by way of the eye, nasal passages, buccal cavity and gastrointestinal tract). Trace amounts (less than 0.01%) of the Sodium cromoglicate does penetrate into the aqueous humour and clearance
from this chamber is virtually complete within 24 hours after treatment is stopped.

In normal volunteers, analysis of drug excretion indicates that approximately 0.03% of Sodium cromoglicate is absorbed following administration to the eye.

5.3 Preclinical safety data
None.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Disodium edetate
Benzalkonium chloride
Purified water.

6.2 Incompatibilities
None known.

6.3 Shelf life
36 months.

6.4 Special precautions for storage
Store below 30°C and protect from direct sunlight. Discard any remaining contents four weeks after opening.

6.5 Nature and contents of container
Low density polyethylene bottle without lauric diethanolamide and plug with a polypropylene cap with a shrink-type security seal containing 5 ml or 10 ml solution.

6.6 Special precautions for disposal
None.

7 MARKETING AUTHORITYHISATION HOLDER
Aventis Pharma Ltd
50 Kings Hill Avenue
Kings Hill
West Malling
Kent ME19 4AH
United Kingdom

or trading as:-

Sanofi-aventis
One Onslow Street
Guildford
Surrey
GU1 4YS
UK

8 MARKETING AUTHORISATION NUMBER(S)
PL 04425/0628

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION
16/02/2009

10 DATE OF REVISION OF THE TEXT
16/02/2009
Is this leaflet hard to see or read? Phone 01483 505515 for help
Read all of this leaflet carefully because it contains important information for you.
This medicine is available without prescription. However, you still need to use Opticrom Hayfever carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:
1. What Opticrom Hayfever is and what it is used for
2. Before you use Opticrom Hayfever
3. How to use Opticrom Hayfever
4. Possible side effects
5. How to store Opticrom Hayfever
6. Further information

1. What Opticrom Hayfever is and what it is used for

Opticrom Hayfever 2% w/v Eye Drops (called Opticrom Hayfever in this leaflet) contain a medicine called sodium cromoglicate. This belongs to a group of medicines called anti-allergics.

It works by stopping the release of the natural substances in your eyes that can lead to an allergic reaction. Signs of an allergic reaction include itchy, watery, red or inflamed eyes and puffy eyelids.

Opticrom Hayfever is used for the relief and treatment of eye allergies. These allergies can happen:
- At any time of the year and is called ‘perennial allergic conjunctivitis’
- In different seasons of the year caused by different pollens. This is called ‘seasonal allergic conjunctivitis’ or hay fever.

2. Before you use Opticrom Hayfever

Do not use this medicine and tell your doctor or pharmacist if:
- You are allergic (hypersensitive) to sodium cromoglicate, or any of the other ingredients of Opticrom Hayfever (listed in Section 6. Further information).
- Signs of an allergic reaction include: a rash, swelling or breathing problems, swelling of your lips, face, throat, tongue and worsening of redness, itching or swelling of the eye or eyelid.

Do not use this medicine if the above applies to you. If you are not sure, talk to your doctor or pharmacist before using Opticrom Hayfever.

Take special care with Opticrom Hayfever if:
- You wear soft contact lenses. You should not wear contact lenses while using these drops.
- If you are not sure if the above applies to you, talk to your doctor or pharmacist before using Opticrom Hayfever.

Pregnancy and breast-feeding
Talk to your doctor before using this medicine if you are pregnant, might become pregnant or think you may be pregnant.
If you are breast-feeding, or planning to breast-feed, talk to your doctor or pharmacist before taking or using any medicine.

Driving and using machines
You may have blurred eyesight straight after using this medicine. If this happens, do not drive or use any tools or machines until you can see clearly.

Important information about some of the ingredients of Opticrom Hayfever
Opticrom Hayfever contains benzalkonium chloride. This may cause your eyes to become irritated. It may also change the colour of your contact lenses.

3. How to use Opticrom Hayfever

Always use Opticrom Hayfever exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

How to use this medicine
- Wash your hands.
- Remove the cap from the bottle.
- Tilt your head back.
- Squeeze one or two drops inside the lower lid without touching your eye.
- Close your eye.
- Wipe away any excess liquid from the eyes with a clean tissue.
- Always put the cap back on the bottle as soon as you have used it.
- Rejoice in the other eye if needed.

How much to use
- One or two drops in each eye four times a day, or as directed by your doctor.
- If your symptoms worsen or do not improve, talk to your doctor or pharmacist.

If you forget to use Opticrom Hayfever
- If you forget a dose, use your drops as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose.
- Do not use a double dose to make up for a forgotten dose.

If you think you have used too much
If you think you have used too much contact your doctor or pharmacist for advice.

4. Possible side effects

Some side effects may occur with this medicine. They usually do not mean anything serious and your doctor or pharmacist has probably prescribed this medicine to benefit you more than it may cause harm.

If any side effects happen, talk to your doctor or pharmacist about using less of this medicine or stopping treatment completely.

5. How to store Opticrom Hayfever

- Store below 25°C.
- Keep out of the reach and sight of children.
- Do not use Opticrom Hayfever if the expiry date on the bottle has passed.
- Do not use Opticrom Hayfever if the packaging shows any signs of tampering or damage.

Further information
- The active ingredient of Opticrom Hayfever is sodium cromoglicate.
- The inactive ingredients are: water, benzalkonium chloride,
- sodium hydroxide, potassium hydroxide, sodium chloride, polysorbate 80 (emulsifier), hydroxypropyl methylcellulose.

6. Further information

- The maximum dose is 4 drops a day.
- Opticrom Hayfever is available only with a prescription from your doctor or pharmacist.
- This leaflet has been written in the hope that it will help you understand your medicine.
- Your doctor or pharmacist has prescribed this medicine for you.
- This leaflet does not take the place of advice from your doctor or pharmacist.
- This leaflet has been written in the hope that it will help you understand your medicine.
- Your doctor or pharmacist has prescribed this medicine for you.
If you stop using Opticrom Hayfever
You should keep using these drops if you are still around the
things that you are allergic to. If you stop using Opticrom Hayfever,
your allergy symptoms may come back.

⚠️ If you have any further questions on the use of this
product, ask your doctor or pharmacist.

4. Possible side effects
Like all medicines, Opticrom Hayfever can cause side effects,
although not everybody gets them.

Stop using Opticrom Hayfever and see a doctor as soon as
possible if:
• The itching, redness or swelling gets worse. You may be
allergic to these drops.

Talk to your doctor or pharmacist if any of the side effects
gets serious or lasts longer than a few days, or if you notice
any side effects not listed in this leaflet:
• Stinging or burning in your eyes or blurring of eyesight. This
should only last for a short time and occurs immediately after
using the eye drops.
• Mild eye irritation

5. How to store Opticrom Hayfever
Keep this medicine in a safe place where children cannot see
or reach it.
Do not use Opticrom Hayfever after the expiry date which is stated
on the label and carton. The expiry date refers to the last day
of that month.
Store below 30°C. Keep the bottle in the outer carton in order
to protect from light.
Opticrom Hayfever is sterile when you buy it, so you must not keep
it for more than four weeks after opening the bottle.
Medicines should not be disposed of via wastewater or
household waste. Ask your pharmacist how to dispose of
medicines no longer required. These measures will help to
protect the environment.

6. Further information
What Opticrom Hayfever contains
• The solution contains 2.0% w/v of the active substance,
sodium cromoglicate.
• The other ingredients are disodium edetate, benzalkonium
chloride and purified water.

What Opticrom Hayfever looks like and contents of the pack
Opticrom Hayfever is a clear colourless to pale yellow solution
supplied in a 5ml or 10 ml plastic dropper bottle with a tamper-
proof cap.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Sanofi-aventis, One Oondo Street, Guildford, Surrey, GU1 4YS, UK
Tel: 01483 505515
Fax: 01483 555452
email: uk-medicalinformation@sanofi-aventis.com

Manufacturer
Sanofi Winthrop Industrie, Boulevard Industriel, 76580 Le Trait,
France

This leaflet does not contain all the information about your
medicine. If you have any questions or are not sure about
anything, ask your doctor or pharmacist.

This leaflet was last revised in July 2008
© Sanofi-aventis, 2001 - 2008
5 ml carton:

DOSAGE:
1 or 2 drops into each eye 4 times daily, or as directed by your doctor. Always read the label before taking this medicine.

Do not use this product if you are sensitive to any ingredient. (Listed on the side of the carton.)

Soft contact lenses should not be worn whilst using this product.

SEE YOUR DOCTOR OR PHARMACIST IF SYMPTOMS WORSEN OR PERsist FOR MORE THAN 48 HOURS.
KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.
Store below 30°C.
Keep the bottle in the outer carton.
Use within four weeks of opening.

CONTAINS:
Sodium Cromoglicate 2% w/v (active ingredient).
Other ingredients:
benzalkonium chloride, disodium edetate, purified water.
Opticrom is a registered Trade Mark.
For the relief and treatment of itchy, irritated, allergic eyes due to hayfever, house mites and other particles e.g. pet hairs.

For external use only

PL 04425/0628
5 ml carton with Braille:
Labels: