ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

OPATANOL 1 mg/mL eye drops, solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One mL of solution contains 1 mg olopatadine (as hydrochloride).

Excipient(s) with known effect: Benzalkonium chloride 0.1 mg/ml

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye drops, solution (eye drops).

Clear, colourless solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of ocular signs and symptoms of seasonal allergic conjunctivitis.

4.2 Posology and method of administration

Posology
The dose is one drop of OPATANOL in the conjunctival sac of the affected eye(s) twice daily (8 hourly). Treatment may be maintained for up to four months, if considered necessary.

Use in elderly
No dosage adjustment in elderly patients is necessary.

Paediatric patients
OPATANOL may be used in paediatric patients three years of age and older at the same dose as in adults. The safety and efficacy of OPATANOL in children aged under 3 years has not been established. No data are available.

Use in hepatic and renal impairment
Olopatadine in the form of eye drops (OPATANOL) has not been studied in patients with renal or hepatic disease. However, no dosage adjustment is expected to be necessary in hepatic or renal impairment (see section 5.2).

Method of administration
For ocular use only.

After the bottle cap is removed, if the tamper evident snap collar is loose, remove before using the product. To prevent contamination of the dropper tip and solution, care must be taken not to touch the eyelids, surrounding areas, or other surfaces with the dropper tip of the bottle. Keep the bottle tightly closed when not in use.

In case of concomitant therapy with other topical ocular medicines, an interval of five minutes should be allowed between successive applications. Eye ointments should be administered last.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

OPATANOL is an antiallergic/antihistaminic agent and, although administered topically, is absorbed systemically. If signs of serious reactions or hypersensitivity occur, discontinue the use of this treatment.

OPATANOL contains benzalkonium chloride which may cause eye irritation.

Benzalkonium chloride has also been reported to cause punctate keratopathy and/or toxic ulcerative keratopathy. Close monitoring is required with frequent or prolonged use in dry eye patients, or in conditions where the cornea is compromised.

Contact lenses
Benzalkonium is known to discolour soft contact lenses. Avoid contact with soft contact lenses. Patients should be instructed to remove contact lenses prior to administration of the eye drop and wait at least15 minutes after instillation before re-inserting contact lenses.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies with other medicinal products have been performed.

In vitro studies have shown that olopatadine did not inhibit metabolic reactions which involve cytochrome P-450 isozymes 1A2, 2C8, 2C9, 2C19, 2D6, 2E1 and 3A4. These results indicate that olopatadine is unlikely to result in metabolic interactions with other concomitantly administered active substances.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no or limited amount of data from the use of ophthalmic olopatadine in pregnant women.

Studies in animals have shown reproductive toxicity following systemic administration (see section 5.3).

Olopatadine is not recommended during pregnancy and in women of childbearing potential not using contraception.

Breast-feeding
Available data in animals have shown excretion of olopatadine in milk following oral administration (for details see section 5.3).

A risk to the newborn/infants cannot be excluded.

OPATANOL should not be used during breast-feeding.

Fertility
Studies have not been performed to evaluate the effect of topical ocular administration of olopatadine on human fertility.

4.7 Effects on ability to drive and use machines

OPATANOL has no or negligible influence on the ability to drive and use machines.

As with any eye drop, temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs at instillation, the patient must wait until the vision clears before driving or using machinery.

4.8 Undesirable effects

Summary of safety profile
In clinical studies involving 1680 patients, OPATANOL was administered one to four times daily in both eyes for up to four months as monotherapy or adjunctive therapy to loratadine 10 mg. Approximately 4.5% of patients can be expected to experience adverse reactions associated with the use of OPATANOL; however, only 1.6% of patients discontinued from the clinical studies due to these adverse reactions. No serious ophthalmic or systemic adverse reactions related to OPATANOL were reported in clinical studies. The most frequent treatment-related adverse reaction was eye pain, reported at an overall incidence of 0.7%.

Tabulated list of adverse reactions
The following adverse reactions have been reported during clinical studies and post-marketing data and are classified according to the following convention: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1000)very rare (<1/10,000) or not known (cannot be estimated from the available data). Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

System Organ Classification	**Frequency**	**Adverse Reactions**
Infections and infestations	Uncommon	rhinitis
Immune system disorders	Not known	hypersensitivity, swelling face
Nervous system disorders	Common	headache, dysgeusia
	Uncommon	dizziness, hypoaesthesia
	Not known	somnolence
Eye disorders	Common	eye pain, eye irritation, dry eye, abnormal sensation in eyes
	Uncommon	corneal erosion, corneal epithelium defect, corneal epithelium disorder, punctate keratitis, keratitis, corneal staining, eye discharge, photophobia, vision blurred, visual acuity reduced, blepharospasm, ocular discomfort, eye pruritus, conjunctival follicles, conjunctival disorder, foreign body sensation in eyes, lacrimation increased, erythema of eyelid, eyelid oedema, eyelid disorder, ocular hyperaemia
	Not known	corneal oedema, eye oedema, eye swelling, conjunctivitis, mydriasis, visual disturbance, eyelid margin crusting
Respiratory, thoracic, and mediastinal disorders	Common	nasal dryness
	Not known	dyspnoea, sinusitis
Gastrointestinal disorders	Not known	nausea, vomiting,
Skin and subcutaneous tissue disorders	Uncommon	dermatitis contact, skin burning sensation, dry skin

	Not known	dermatitis, erythema
General disorders and administration site conditions	Common	fatigue
	Not known	asthenia, malaise

Cases of corneal calcification have been reported very rarely in association with the use of phosphate containing eye drops in some patients with significantly damaged corneas.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

4.9 Overdose

No data are available in humans regarding overdose by accidental or deliberate ingestion. Olopatadine has a low order of acute toxicity in animals. Accidental ingestion of the entire contents of a bottle of OPATANOL would deliver a maximum systemic exposure of 5 mg olopatadine. This exposure would result in a final dose of 0.5 mg/kg in a 10 kg infant, assuming 100% absorption.

Prolongation of the QTc interval in dogs was observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use. A 5 mg oral dose was administered twice-daily for 2.5 days to 102 young and elderly male and female healthy volunteers with no significant prolongation of QTc interval compared to placebo. The range of peak steady-state olopatadine plasma concentrations (35 to 127 ng/ml) seen in this study represents at least a 70-fold safety margin for topical olopatadine with respect to effects on cardiac repolarisation.

In the case of overdose, appropriate monitoring and management of the patient should be implemented.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: ophthalmologicals; decongestant and antiallergics; other antiallergics.

ATC code: S01GX 09

Olopatadine is a potent selective antiallergic/antihistaminic agent that exerts its effects through multiple distinct mechanisms of action. It antagonises histamine (the primary mediator of allergic response in humans) and prevents histamine induced inflammatory cytokine production by human conjunctival epithelial cells. Data from *in vitro* studies suggest that it may act on human conjunctival mast cells to inhibit the release of pro-inflammatory mediators. In patients with patent nasolacrimal ducts, topical ocular administration of OPATANOL was suggested to reduce the nasal signs and symptoms that frequently accompany seasonal allergic conjunctivitis. It does not produce a clinically significant change in pupil diameter.

5.2 Pharmacokinetic properties

Absorption
Olopatadine is absorbed systemically, as are other topically administered medicinal products. However, systemic absorption of topically applied olopatadine is minimal with plasma concentrations ranging from below the assay quantitation limit (<0.5 ng/ml) up to 1.3 ng/ml. These concentrations are 50-to 200-fold lower than those following well tolerated oral doses.

Elimination
From oral pharmacokinetic studies, the half-life of olopatadine in plasma was approximately eight to 12 hours, and elimination was predominantly through renal excretion. Approximately 60-70% of the dose was recovered in the urine as active substance. Two metabolites, the mono-desmethyl and the N-oxide, were detected at low concentrations in the urine.

Since olopatadine is excreted in urine primarily as unchanged active substance, impairment of renal function alters the pharmacokinetics of olopatadine with peak plasma concentrations 2.3-fold greater in patients with severe renal impairment (mean creatinine clearance of 13.0 ml/min) compared to healthy adults. Following a 10 mg oral dose in patients undergoing haemodialysis (with no urinary output), plasma olopatadine concentrations were significantly lower on the haemodialysis day than on the non-haemodialysis day suggesting olopatadine can be removed by haemodialysis.

Studies comparing the pharmacokinetics of 10 mg oral doses of olopatadine in young (mean age 21 years) and elderly (mean age 74 years) showed no significant differences in the plasma concentrations (AUC), protein binding or urinary excretion of unchanged parent drug and metabolites.

A renal impairment study after oral dosing of olopatadine has been performed in patients with severe renal impairment. The results indicate that a somewhat higher plasma concentration can be expected with OPATANOL in this population. Since plasma concentrations following topical ocular dosing of olopatadine are 50-to 200-fold lower than after well-tolerated oral doses, dose adjustment is not expected to be necessary in the elderly or in the renally impaired population. Liver metabolism is a minor route of elimination. Dose adjustment is not expected to be necessary with hepatic impairment.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety, pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential and toxicity to reproduction.

Studies in animals have shown reduced growth of nursing pups of dams receiving systemic doses of olopatadine well in excess of the maximum level recommended for human ocular use. Olopatadine has been detected in the milk of nursing rats following oral administration.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride
sodium chloride
disodium phosphate dodecahydrate (E339)
hydrochloric acid (E507) (to adjust pH)
sodium hydroxide (E524) (to adjust pH)
purified water

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf-life

3 years.

Shelf-life after first opening
Discard four weeks after first opening.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and content of container

5 ml opaque low density polyethylene bottles with polypropylene screw caps (DROP-TAINER).

Cartons containing 1 or 3 bottles. Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER

Novartis Europharm Limited
Frimley Business Park
Camberley GU16 7SR
United Kingdom

8. MARKETING AUTHORISATION NUMBERS

EU/1/02/217/001-002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17th May 2002
Date of latest renewal: 22nd May 2007

10. DATE OF REVISION OF THE TEXT

Detailed information on this medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu.

ANNEX II

A. MANUFACTURER(S) RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

A. MANUFACTURING AUTHORISATION HOLDERS RESPONSIBLE FOR BATCH RELEASE

Names and addresses of the manufacturer(s) responsible for batch release

S.A. Alcon-Couvreur N.V.,
Rijksweg 14,
B-2870 Puurs,
Belgium.

or

Alcon Cusí, S.A.,
Camil Fabra 58,
08320 El Masnou,
Barcelona,
Spain.

The printed package leaflet of the medicinal product must state the name and address of the manufacturer responsible for the release of the concerned batch.

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IMPOSED ON THE MARKETING AUTHORISATION HOLDER

Medicinal product subject to medical prescription

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

The marketing authorisation holder shall submit periodic safety update reports for this product in accordance with the requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and published on the European medicines web-portal.

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

- **Risk Management Plan (RMP)**

The MAH shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the Marketing Authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:

- At the request of the European Medicines Agency;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

If the dates for submission of a PSUR and the update of a RMP coincide, they can be submitted at the same time.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

BOX OF 1 BOTTLE + BOX OF 3 BOTTLES

1. NAME OF THE MEDICINAL PRODUCT

OPATANOL 1 mg/mL eye drops, solution
Olopatadine

2. STATEMENT OF ACTIVE SUBSTANCE

1 mL of solution contains 1 mg olopatadine (as hydrochloride).

3. LIST OF EXCIPIENTS

Benzalkonium chloride, sodium chloride, disodium phosphate dodecahydrate, hydrochloric acid/sodium hydroxide (to adjust pH) and purified water.

4. PHARMACEUTICAL FORM AND CONTENTS

Eye drops, solution;
1 x 5 mL
3 x 5 mL

5. METHOD AND ROUTE OF ADMINISTRATION

For ocular use. Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

Exp: xx/xxxx
Discard four weeks after first opening.
Opened:
Opened (1):
Opened (2):
Opened (3):

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Novartis Europharm Limited
Frimley Business Park
Camberley GU16 7SR
United Kingdom

12. MARKETING AUTHORISATION NUMBERS

EU/1/02/217/001 1 x 5 mL
EU/1/02/217/002 3 x 5 mL

13. BATCH NUMBER

Lot: xxxxx

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Opatanol

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BOTTLE LABEL

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE OF ADMINISTRATION

OPATANOL 1 mg/mL eye drops.
Olopatadine.

For ocular use.

2. METHOD OF ADMINISTRATION

Read the package leaflet before use.

3. EXPIRY DATE

Exp: xx/xxxx
Discard four weeks after first opening.
Opened:

4. BATCH NUMBER

Lot:

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

5 mL

6 OTHER

B. PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

OPATANOL 1 mg/mL eye drops, solution.
Olopatadine.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions , ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What OPATANOL is and what it is used for

OPATANOL is used for the treatment of signs and symptoms of seasonal allergic conjunctivitis.

Allergic conjunctivitis. Some materials (allergens) like pollens, house dust or animal fur may cause allergic reactions resulting in itching, redness as well as swelling of the surface of your eye.

OPATANOL is a medicine for treatment of allergic conditions of the eye. It works by reducing the intensity of the allergic reaction.

2. What you need to know before you use OPATANOL

Do not use OPATANOL
- **If you are allergic** (hypersensitive) to olopatadine or any of the other ingredients of this medicine (listed in section 6).
- You should not use OPATANOL if you are breast-feeding.

Warnings and precautions
Talk to your doctor or pharmacist before using OPATANOL.

You should remove contact lenses that are in your eyes before using OPATANOL.

Children
- Do not use OPATANOL in children under the age of 3 years. Do not give this medicine to children under the ages of 3 years because there is no data to indicate that it is safe and work in children under 3 years.

Other medicines and OPATANOL
Tell your doctor or pharmacist if you are taking,have recently taken or might take any other medicines.

If you are using other eye drops or eye ointment medicines, leave at least 5 minutes between each medicine. Eye ointments should be administered last.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advise before using this medicine.

You should not use OPATANOL if you are breast-feeding, ask your doctor for advise before using this medicine.

Driving and using machines
You may find that your vision is blurred for a time just after you use OPATANOL. Do not drive or use machines until this has worn off.

OPATANOL contains Benzalkonium chloride
Benzalkonium chloride may cause eye irritation and is known to discolour soft contact lenses, therefore contact with soft contact lenses should be avoided. If you wear contact lens you should remove contact lenses prior to application and wait at least 15 minutes before putting your lenses back in.

3. How to use OPATANOL

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one drop in the eye or eyes, twice a day – morning and evening.

Use this much unless your doctor tells you to do differently. Only use OPATANOL in both eyes if your doctor told you to. Use it for as long as your doctor told you to.

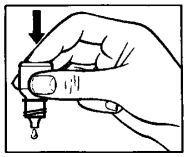
OPATANOL should only be used as an eye drop.

TURN THE PAGE FOR MORE ADVICE

Now turn over>

3. How to use OPATANOL (*continued)*

1



2

How much to use
< see side 1

- Get the OPATANOL bottle and a mirror.
- Wash your hands.
- Take the bottle and twist off the cap.
- After cap is removed, if the tamper evident snap collar is loose, remove before using the product.

- Hold the bottle, pointing down, between your thumb and middle finger.
- Tilt your head back. Pull down your eyelid with a clean finger, until there is a 'pocket' between the eyelid and your eye. The drop will go in here (picture 1).
- Bring the bottle tip close to the eye. Use the mirror if it helps.
- Don't touch your eye or eyelid, surrounding areas or other surfaces with the dropper. It could infect the drops left in the bottle.
- Gently press on the base of the bottle to release one drop of OPATANOL at a time.
- Don't squeeze the bottle, it is designed so that just a gentle press on the bottom is needed (picture 2).
- If you use drops in both eyes, repeat the steps for your other eye.
- Put the bottle cap back on firmly immediately after use.

If a drop misses your eye, try again.

If you use more OPATANOL than you should
Rinse it all out with warm water. Do not put in any more drops until it's time for your next regular dose.

If you forget to use OPATANOL
Use a single drop as soon as you remember, and then go back to your regular dosing routine. However, if it is almost time for your next dose, skip the missed dose before going back to your regular dosing routine. Do not use a double dose to make up for the one missed.

If you stop using OPATANOL
Do not stop using this medicine without first speaking to your doctor.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects have been seen with OPATANOL

Common: ***may affect up to 1 in 10 people***

Effects in the eye: eye pain, eye irritation, dry eye, abnormal eye sensation, eye discomfort

General side effects: headache, fatigue, dry nose, bad taste

Uncommon: may affect up to 1 in 100 people

Effects in the eye: blurred, reduced, or abnormal vision, corneal disorder, eye surface inflammation with or without surface damage, inflammation or infection of the conjunctiva, eye discharge, sensitivity to light, increased tear production, itchy eye, redness of the eye, eyelid abnormality, itching, redness, swelling, or crusting of the eyelid.

General side effects: abnormal or decreased sensation, dizziness, runny nose, dry skin, skin inflammation.

Not known: frequency cannot be estimated from the available data

Effects in the eye: eye swelling, corneal swelling, change in pupil size

General side effects: shortness of breath, increased allergic symptoms, facial swelling, drowsiness, generalized weakness, nausea, vomiting, sinus infection, skin redness and itching.

In very rare cases, some patients with severe damage to the clear layer at the front of the eye (the cornea) have developed cloudy patches on the cornea due to calcium build-up during treatment.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store OPATANOL

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle and the box after 'Exp'. The expiry date refers to the last day of the month.

This medicine does not require any special storage conditions.

You should throw away the bottle four weeks after you first opened it to prevent infections, and use a new bottle. Write down the date you opened it in the space on each bottle label and box

Do not throw away medicines via waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Content of the pack and other information

What OPATANOL contains

- The active substance is olopatadine. Each mL of solution contains 1mg of olopatadine (as hydrochloride).

  The other ingredients are benzalkonium chloride, sodium chloride, disodium phosphate dodecahydrate (E339), hydrochloric acid (E507) and/or sodium hydroxide (E524) and purified water.

What OPATANOL looks like and contents of the pack
OPATANOL is a clear and colourless liquid (a solution) supplied in a pack containing either one 5 ml bottle or three 5 ml plastic bottles with screw caps. Not all pack sizes may be marketed.

The marketing authorisation holder	Manufacturer	Manufacturer
Novartis Europharm Limited Frimley Business Park Camberley GU16 7SR United Kingdom	S.A. Alcon –Couvreur N.V. Rijksweg 14 B-2870 Puurs Belgium	Alcon Cusí. S.A. Camil Fabra 58 08320 El Masnou Spain

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

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This leaflet was last approved on XXXXX

Detailed information on this medicine is available on the European Medicines Agency website: http://www.emea.europa.eu/