Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT
MAXIDEX 1 mg/ml eye drops, suspension.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Dexamethasone 1.0 mg/ml.
Excipient with known effect: 1 ml suspension contains 0.1 mg benzalkonium chloride
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Eye drops, suspension.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
Steroid responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe; suppressing the reaction on transplant in keratoplasty.

4.2 Posology and method of administration
Shake well before use.

Topical application. 1 to 2 drops in the conjunctival sac.
In severe inflammation, the instillations may be made hourly and subsequently at longer intervals until the treatment is discontinued as soon as the inflammation has subsided. In less severe inflammation, the drops may be administered 4 to 6 times daily.

Do not stop the treatment prematurely. In the case of glaucoma, the duration of the treatment must be limited to 2 weeks, unless a prolongation is justified (see "4.4 Special warnings and precautions for use").

4.3 Contraindications
Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1
Herpetic keratitis (dendritic keratitis), vaccinia, varicella and other viral diseases of the cornea and the conjunctiva; tuberculous lesions; untreated bacterial infections of the eye; fungal diseases of the eye structures; and in patients who are hypersensitive to any of the components of these preparations.

Corticoids should not be used after uncomplicated removal of a corneal foreign body or with infections or injuries limited to the superficial corneal epithelium.

4.4 Special warnings and precautions for use
Not to be used without medical verification. To be prescribed and renewed only after examination by slit lamp biomicroscopy and a fluorescein test.

This medication is not effective in the treatment of Sjogren's keratoconjunctivitis.

Excessive and/or prolonged use of ophthalmic steroids increases the risk of ocular complications and could cause systemic side effects. If the inflannmatory condition does not respond within a reasonable period during the course of the therapy, other forms of therapy should be instituted to reduce these risks.

Prolonged use of ophthalmic steroids may result in ocular hypertension and/or glaucoma,

with damage to the optic nerve, defects in visual acuity and field of vision, and posterior subcapsular cataract formation. A patient with a family or personal history of glaucoma has a higher risk of a corticosteroid-induced rise in intraocular pressure. If these products are used for 10 days or longer, intraocular pressure should be routinely monitored even
though it may be difficult in children and uncooperative patients. Patients with glaucoma should be monitored weekly.

Corticosteroids may mask infection or exacerbate an existing infection. Prolonged use may suppress the immune response and thus increase the hazard of secondary ocular infection. Appropriate antibiotic therapy should be instituted for concurrent bacterial infections. The possibility of persistent fungal infections of the cornea should be considered after prolonged corticosteroid dosing.

Ocular herpes simplex has occurred in patients under systemic or local corticosteroid therapy for other conditions. Using corticosteroid medication in the treatment of herpes simplex other than epithelial herpes simplex keratitis, in which it is contraindicated, requires great caution; periodic slit-lamp microscopy is essential.

In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical corticosteroids.

The treatment should not be discontinued prematurely as a flare-up of the inflammatory condition may occur with the sudden interruption of highly dosed corticosteroids.
Wearing contact lenses (hard or soft) is discouraged during treatment with topical ophthalmic corticosteroids. Additionally, the preservative benzalkonium chloride can be adsorbed by soft contact lenses and may discolour lenses or cause eye irritation.
MAXIDEX should not be instilled while wearing contact lenses.

After application of the eye drops following measures are useful to reduce systemic resorption:
- Keep the eyelid closed for 2 minutes.
Close the lacrimal duct with the finger for 2 minutes.

4.5 Interaction with other medicinal products and other forms of interaction
When using pupil-dilating eye drops (atropine and other anticholinergic substances), which may cause elevation of intraocular pressure, concomitant use of MAXIDEX may lead to an additional elevation of intraocular pressure.
If supplementary eye preparations are to be used, one should wait about 15 minutes between 2 applications.

4.6 Fertility, pregnancy and lactation
Pregnancy
The safety of long-term or intensive treatment with topical corticosteroids in pregnant women has not been established. The product should therefore only be used with restraint during pregnancy, and only in cases of real necessity.

Lactation
A short-term (1 to 2 weeks) low-dose treatment with eye drops containing corticosteroids may be considered during lactation if clearly needed. Glucocorticoids are excreted into human milk. Hence nursing should be discontinued if substantial doses or prolonged treatment are required.

4.7 Effects on ability to drive and use machines
As with any eye preparation, temporarily 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

The following adverse effects have been reported following use of this or other topical ophthalmic steroid preparations:

Eye disorders
Rare (≥ 0.01% < 0.1%): eye irritation, visual acuity reduced, subcapsular cataract, glaucoma, visual field defects.

Immune System Disorders
Rare (≥ 0.01% < 0.1%): hypersensitivity.

Infections and Infestations
Rare (≥ 0.01% < 0.1%): eye infection (exacerbation or secondary).

Injury, Poisoning and Procedural Complications
Very Rare (< 0.01%): corneal perforation.

Investigations
Uncommon (k 0.1% <1%): intraocular pressure increased.

4.9 Overdose
A topical overdose is not likely to be associated with toxicity. A topical overdose of MAXIDEX in the eye(s) can be washed out with tepid water. Treatment of an accidental oral ingestion is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: corticosteroids.
ATC code: S01BA01

Dexamethasone is one of the most potent corticosteroids. This high degree of activity is the result of adding a methyl radical and a fluor atom to the prednisolone molecule. This synthetic glucocorticoid inhibits the inflammatory response to agents of a mechanica!, chemical or immunological nature. Up to the present, no generally accepted explanation of that property has been found.

5.2 Pharmacokinetic properties
The corticosteroids are absorbed in the aqueous humor, the cornea, the iris, and the ciliary body. Certain systemic resorption may occur, which is not of great significance unless large doses are administered or with long-term use in children.

5.3 Preclinical safety data
No data provided.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Benzalkonium chloride 0.1 mg — hydroxypropyl methylcellulose — disodium phosphate anhydrous — polysorbate 80 — disodium edetate — sodium chloride — citric acid monohydrate and/or sodium hydroxide — purified water to 1 ml.

6.2 Incompatibilities
None known.

6.3 Shelf-life
Unopened: 24 months.
See expiry date on the packaging after the sign "Exp" (month/year).
Discard this medicine one month (28 days) after first opening of the bottle.

6.4 Special precautions for storage
Do not store above 25°C. For storage conditions after first opening of the medicinal product, see section 6.3.

6.5 Nature and contents of container
5 ml droptainer.

6.6 Special precautions for disposal
No special requirements.

Manufacturer
Alcon Couvreur N.V. Belgium

License Holder
Lapidot Medical Import and Marketing LTD