Summary of Product Characteristics

MOXINAL-D

(Moxifloxacin 0.5% w/v and Dexamethasone 0.1% w/v Eye Drops, Solution)

1 Name of the medicinal product

MOXINAL-D – Moxifloxacin 0.5% w/v and Dexamethasone 0.1% w/v Eye Drops, Solution

2 Qualitative and quantitative composition

Each ml of solution contains moxifloxacin hydrochloride equivalent to moxifloxacin 5 mg (0.5% w/v) and dexamethasone 1 mg (0.1% w/v).

Excipient(s) with known effect
Each ml contains boric acid 2 mg (0.2% w/v) and benzalkonium chloride 0.4 mg (0.04% w/v).

For the full list of excipients, see section 6.1.

3 Pharmaceutical form

Eye drops, solution.

A pale yellow solution.

4 Clinical particulars

4.1 Therapeutic indications

MOXINAL-D is indicated for the treatment of steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where bacterial infection, or a risk of bacterial ocular infection, exists. It may also be used for post-operative inflammation and for other ocular inflammation associated with infection.

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

4.2 Posology and method of administration

Posology

Adults, including the elderly
One or two drops instilled into the conjunctival sac(s) every 4 to 6 hours. During the initial 24 to 48 hours the dosage may be increased to one or two drops every two hours. The frequency should be decreased gradually as warranted by improvement in clinical signs. Care should be taken not to discontinue therapy prematurely.

Treatment should be reviewed regularly and continued only for as long as clinically necessary; prolonged use increases the risk of corticosteroid-related adverse effects (see section 4.4).

Renal and hepatic impairment
No dose adjustment is considered necessary, as systemic exposure following topical ocular administration is low.

Paediatric population
The safety and efficacy of MOXINAL-D in children have not been established. Prolonged use of topical corticosteroids in children may result in adrenal suppression (see section 4.4).

Method of administration
For ocular use only. Not for injection: the solution must not be injected subconjunctivally or introduced directly into the anterior chamber of the eye.

To prevent contamination of the dropper tip and the solution, care must be taken not to touch the eyelids, surrounding areas or other surfaces with the dropper tip. Patients should be instructed to keep the bottle tightly closed when not in use.

Nasolacrimal occlusion, or gently closing the eyelid, for 2 to 3 minutes after instillation is recommended, as this may reduce systemic absorption and the risk of systemic adverse reactions. If more than one topical ophthalmic medicinal product is being used, the products should be administered at least 5 minutes apart; eye ointments should be administered last.

4.3 Contraindications

- Hypersensitivity to the active substances, to other quinolones, or to any of the excipients listed in section 6.1.
- Epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella and other viral diseases of the conjunctiva and cornea.
- Mycobacterial infection of the eye.
- Fungal diseases of ocular structures.
- Untreated purulent ocular infection where a corticosteroid alone would be inappropriate.

4.4 Special warnings and precautions for use

For topical ocular use only. Not for injection.

Prolonged corticosteroid use

Prolonged use of topical corticosteroids may result in ocular hypertension and/or glaucoma, with damage to the optic nerve, defects in visual acuity and fields of vision, and posterior subcapsular cataract formation. Intraocular pressure should be monitored routinely if the product is used for 10 days or longer, and this is particularly important in paediatric patients, as the risk of corticosteroid-induced ocular hypertension may be greater in children and may occur earlier than in adults.

Prolonged use may also suppress the host immune response and thereby increase the hazard of secondary ocular infections, including fungal and viral infections. Fungal infection of the cornea should be suspected in any persistent corneal ulceration where a corticosteroid has been used or is in use; fungal cultures should be taken where appropriate.

Corneal and scleral thinning

Topical corticosteroids may slow corneal wound healing. In diseases causing thinning of the cornea or sclera, perforation has been known to occur with the use of topical corticosteroids. Caution is required in patients with a history of ocular herpes simplex, in whom corticosteroids may prolong the course and exacerbate the severity of the infection.

Systemic corticosteroid effects

Systemic absorption may occur with topical ocular corticosteroids. Cushing’s syndrome and/or adrenal suppression associated with systemic absorption of ocular dexamethasone may occur after intensive or long-term continuous therapy in predisposed patients, including children and patients treated with CYP3A4 inhibitors (including ritonavir and cobicistat). In these cases, treatment should be discontinued progressively.

Visual disturbance

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, referral to an ophthalmologist should be considered for evaluation of possible causes, which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy.

Hypersensitivity to fluoroquinolones

In patients receiving systemically administered quinolones, including moxifloxacin, serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported, some following the first dose. Some reactions were accompanied by cardiovascular collapse, loss of consciousness, angioedema (including laryngeal, pharyngeal or facial oedema), airway obstruction, dyspnoea, urticaria and pruritus. If an allergic reaction to moxifloxacin occurs, use of the medicinal product should be discontinued; serious acute hypersensitivity reactions may require immediate emergency treatment.

Tendon disorders
Although plasma concentrations of moxifloxacin following ophthalmic administration are much lower than after therapeutic oral doses, caution should be exercised and treatment should be discontinued at the first sign of tendon inflammation.

Resistance and appropriate use
As with other anti-infectives, prolonged use may result in overgrowth of non-susceptible organisms, including fungi. If superinfection occurs, treatment should be discontinued and alternative therapy instituted. MOXINAL-D should not be used for the prophylaxis or empirical treatment of gonococcal conjunctivitis, including gonococcal ophthalmia neonatorum, because of the prevalence of fluoroquinolone-resistant Neisseria gonorrhoeae; patients with eye infections caused by Neisseria gonorrhoeae should receive appropriate systemic treatment.

Contact lenses
Patients should be advised not to wear contact lenses if they have signs and symptoms of a bacterial ocular infection. This medicinal product contains benzalkonium chloride, which may cause eye irritation and is known to discolour soft contact lenses; contact with soft contact lenses must be avoided. If contact lens wear is permitted by the prescriber, lenses should be removed prior to instillation and not reinserted for at least 15 minutes.

Excipients
This medicinal product contains benzalkonium chloride, which may cause eye irritation, symptoms of dry eye and effects on the tear film and corneal surface. It should be used with caution in patients with dry eye and in patients where the cornea may be compromised. Patients should be monitored in the event of prolonged use.

This medicinal product contains boric acid, which may impair fertility.

4.5 Interaction with other medicinal products and other forms of interaction

No specific interaction studies have been performed with MOXINAL-D. Given the low systemic concentrations of moxifloxacin and dexamethasone following topical ocular administration, systemic drug interactions are unlikely to occur.

Concomitant use of ocular corticosteroids and CYP3A4 inhibitors, including ritonavir and cobicistat-containing products, may increase the risk of systemic corticosteroid adverse effects; the combination should be avoided unless the benefit outweighs the increased risk, in which case patients should be monitored for systemic corticosteroid effects (see section 4.4).

If more than one topical ophthalmic medicinal product is being used, the products should be administered at least 5 minutes apart (see section 4.2).

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no or limited data from the use of moxifloxacin and dexamethasone eye drops in pregnant women. Topically applied corticosteroids can be absorbed systemically and have been shown to cause abnormalities of foetal development in pregnant animals. Although the relevance

of this finding to humans has not been established, the use of MOXINAL-D during pregnancy should be avoided unless considered essential by the physician.

Breast-feeding

It is not known whether moxifloxacin or dexamethasone are excreted in human milk following topical ocular administration; it is possible that traces of dexamethasone will enter the breast milk. MOXINAL-D is not recommended in breast-feeding mothers. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from therapy, taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

Fertility

No studies have been conducted to evaluate the effect of topical ocular administration of moxifloxacin or dexamethasone on human fertility. This medicinal product contains boric acid, which may impair fertility (see section 4.4).

4.7 Effects on ability to drive and use machines

MOXINAL-D has a minor influence on the ability to drive and use machines. As with other eye drops, transient blurred vision or other visual disturbances may affect the ability to drive or use machines. Patients should not drive or use machines until their vision has cleared.

4.8 Undesirable effects

Summary of the safety profile

The most frequently reported adverse reactions with moxifloxacin eye drops are eye irritation, eye pain, increased lacrimation, keratitis and papillary conjunctivitis. The adverse reactions associated with the dexamethasone component relate principally to prolonged corticosteroid use and include raised intraocular pressure, glaucoma, posterior subcapsular cataract, delayed wound healing and secondary ocular infection.

Tabulated list of adverse reactions

Adverse reactions attributable to the individual active substances are listed below by System Organ Class and frequency, tagged by component: (M) moxifloxacin, (D) dexamethasone. Frequencies are defined as: very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1,000 to < 1/100), rare (≥ 1/10,000 to < 1/1,000), very rare (< 1/10,000) and not known (cannot be estimated from the available data).

System Organ Class	Frequency	Adverse reaction
Infections and infestations	Not known	Secondary ocular infection, including bacterial, fungal and viral infection (D)
Immune system disorders	Not known	Hypersensitivity, anaphylactic reaction (M); hypersensitivity (D)
Endocrine disorders	Not known	Adrenal suppression, Cushing's syndrome following intensive or prolonged use (D)
Nervous system disorders	Uncommon	Headache (M)
	Not known	Dizziness, dysgeusia (M)
Eye disorders	Common	Eye pain, eye irritation (M)
	Uncommon	Punctate keratitis, dry eye, conjunctival haemorrhage, ocular hyperaemia, eye pruritus, eyelid oedema, ocular discomfort (M)
	Not known	Increased intraocular pressure, glaucoma, posterior subcapsular cataract, delayed corneal wound healing, corneal or scleral thinning with perforation, mydriasis, ptosis (D)
	Not known	Endophthalmitis, ulcerative keratitis, corneal erosion, corneal abrasion, corneal opacity, corneal infiltrates, corneal deposits, eye allergy, keratitis, conjunctivitis, blepharitis, eye swelling, conjunctival oedema, blurred vision, decreased visual acuity,

System Organ Class	Frequency	Adverse reaction
		asthenopia, photophobia, eyelid erythema, increased lacrimation (M)
Cardiac disorders	Not known	Palpitations (M)
Respiratory, thoracic and mediastinal disorders	Uncommon	Dyspnoea (M, reported in paediatric patients)
	Not known	Laryngeal oedema, airway obstruction (M, quinolone class effect)
Gastrointestinal disorders	Not known	Vomiting (M)
Skin and subcutaneous tissue disorders	Not known	Erythema, rash, pruritus, urticaria (M)

Description of selected adverse reactions

Raised intraocular pressure and cataract formation are the principal risks of prolonged corticosteroid therapy. Intraocular pressure should be monitored routinely where treatment continues for 10 days or longer, and particular vigilance is required in paediatric patients (see section 4.4).

Serious and occasionally fatal hypersensitivity reactions, including anaphylaxis, have been reported with systemically administered quinolones. If an allergic reaction occurs, treatment should be discontinued immediately (see section 4.4).

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 to the National Regulatory Authority.

4.9 Overdose

Overdose by the topical ocular route is unlikely to occur. The total quantity of active substances in a single container is too small to induce systemic effects after accidental ingestion.

In the event of topical overdose, the eye(s) may be flushed with lukewarm water. Excessive or prolonged local application of the corticosteroid component may increase the risk of raised intraocular pressure and other corticosteroid-related ocular effects; treatment is symptomatic and supportive, with monitoring of intraocular pressure as clinically indicated.

5 Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Ophthalmologicals; corticosteroids and anti-infectives in combination; dexamethasone and anti-infectives.

ATC code: S01CA01

Moxifloxacin – mechanism of action

Moxifloxacin, a fourth-generation fluoroquinolone, inhibits the DNA gyrase and topoisomerase IV required for bacterial DNA replication, repair and recombination.

Moxifloxacin – resistance

Resistance to fluoroquinolones, including moxifloxacin, generally occurs by chromosomal mutations in the genes encoding DNA gyrase and topoisomerase IV. In Gram-negative bacteria, moxifloxacin resistance can be due to mutations in the mar (multiple antibiotic resistance) and qnr (quinolone resistance) gene systems. Resistance is also associated with expression of bacterial efflux proteins and inactivating enzymes. Cross-resistance with beta-lactams, macrolides and aminoglycosides is not expected, owing to differences in mode of action.

Dexamethasone – mechanism of action
Dexamethasone is a highly potent and long-acting glucocorticoid, with approximately seven times greater anti-inflammatory potency than prednisolone. The actions of corticosteroids are mediated by binding of the corticosteroid molecules to receptor molecules located within sensitive cells; corticosteroid receptors are present in human trabecular meshwork cells and in rabbit iris ciliary body tissue.

Corticosteroids inhibit phospholipase A2, thereby preventing the generation of substances which mediate inflammation, for example prostaglandins. Corticosteroids also produce a marked, though transient, lymphocytopenia; this depletion is due to redistribution of the cells, with T-lymphocytes being affected to a greater degree than B-lymphocytes. Lymphokine production is reduced, as is the sensitivity of macrophages to activation by lymphokines. Corticosteroids also retard epithelial regeneration, diminish post-inflammatory neovascularisation, and reduce towards normal levels the excessive permeability of inflamed capillaries.

5.2 Pharmacokinetic properties

Moxifloxacin
Following topical ocular administration, moxifloxacin is absorbed into the systemic circulation. Plasma concentrations of moxifloxacin were measured in 21 male and female subjects who received bilateral topical ocular doses three times a day for 4 days. The mean steady-state Cmax and AUC were 2.7 ng/ml and 41.9 ng·h/ml respectively. These exposure values are approximately 1,600-fold and 1,200-fold lower than the mean Cmax and AUC reported after therapeutic 400 mg oral doses of moxifloxacin. The plasma half-life of moxifloxacin was estimated to be 13 hours.

Dexamethasone – absorption
When given topically to the eye, dexamethasone is absorbed into the aqueous humour, cornea, iris, choroid, ciliary body and retina. Systemic absorption occurs, but may be significant only at higher dosages or during extended paediatric therapy. Up to 90% of dexamethasone is absorbed when given by mouth, with peak plasma levels reached between 1 and 2 hours after ingestion and showing wide individual variation.

Dexamethasone – distribution
Tissue distribution studies in animals show a high uptake of dexamethasone by the liver, kidney and adrenal glands; a volume of distribution of 0.58 l/kg has been quoted. Up to 77% of dexamethasone is bound to plasma proteins, mainly albumin; unlike cortisol, this percentage remains practically unchanged with increasing steroid concentrations.

Dexamethasone – biotransformation and elimination
The mean plasma half-life of dexamethasone is 3.6 ± 0.9 hours. In humans, over 60% of circulating steroid is excreted in the urine within 24 hours, largely as unconjugated steroid. Dexamethasone appears to be cleared more rapidly from the circulation of the foetus and neonate than from that of the mother; plasma dexamethasone levels in the foetus and the mother have been found in a ratio of 0.32 to 1.

5.3 Preclinical safety data

The use of corticosteroids, including dexamethasone, in ophthalmology is well established, and the breadth of clinical experience confirms its suitability as a topical ophthalmic agent. Little relevant additional toxicology has been reported.

Non-clinical data for moxifloxacin reveal no special hazard for humans at the exposures achieved following topical ocular administration, based on conventional studies of safety pharmacology, repeated-dose toxicity, genotoxicity and toxicity to reproduction. As with other quinolones, moxifloxacin has been shown to cause articular cartilage lesions in immature animals following

systemic administration at exposures substantially in excess of those achieved by the ophthalmic route.

6 Pharmaceutical particulars

6.1 List of excipients

- Boric acid
- Macrogol 400 (polyethylene glycol 400)
- Benzalkonium chloride
- Betadex (beta-cyclodextrin)
- Glycerol
- Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 30°C. Do not freeze. Protect from light.

Keep out of the sight and reach of children.

6.5 Nature and contents of container

White plastic LDPE vial containing 5 ml of solution, sealed and packed in a carton with a package insert.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

For single-patient use only. The container should be discarded after the completion of treatment.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 Marketing authorisation holder

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8 Marketing authorisation number

CTD13203

9 Date of first authorisation/renewal of the authorisation

23.07.2026

10 Date of revision of the text

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