Summary of Product Characteristics

1. Name of the medicinal product :

ONAMOX-D

Moxifloxacin & Dexamethasone Sodium Phosphate Ophthalmic Solution

2. Qualitative and Quantitative composition:

Composition:

Moxifloxacin Hydrochloride USP
Eq. To Moxifloxacin… ..... % w/v
Dexamethasone Sodium Phosphate USP
Eq. To Dexamethasone Phosphate.....% w/v
Benzalkonium Chloride Solution USP ..... % w/v
(As Preservative)
Sterile aqueous base..... q.s

Excipient with known effect
This eye drops contains total Sodium content 8.93 mg per 5 ml bottle.

3. Pharmaceutical Form: Eye Drops

Description: Yellow colour clear solution filled in 5 ml LDPE bottle.

4. Clinical Particulars:

4.1 Therapeutic indications

In post-surgery infection

• Inflammation

4.2 Posology and method of administration

Instil one drop in the affected eye 3 times a day for 5 to 7 days

4.3 Contraindications

Moxifloxacin and Dexamethasone Sodium Phosphate Ophthalmic Solution is contraindicated in patients with a history of hypersensitivity to Moxifloxacin, to other quinolones, to Dexamethasone, or to any of the components in this medication.

4.4 Special warnings and precautions for use

Moxifloxacin and Dexamethasone Sodium Phosphate Ophthalmic Solution should not be injected subconjunctivally, nor should it be introduced directly into the anterior chamber of the eye.

• In patients receiving systemically administered quinolones, including Moxifloxacin, serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported, some following the first dose.

• If an allergic reaction to Moxifloxacin or Dexamethasone occurs, discontinue use of the drug. Serious acute hypersensitivity reactions may require immediate emergency treatment.

• Stress and intercurrent illness in patients on corticosteroid therapy subjected to unusual stress (from trauma or infection), increased dosage of rapidly acting corticosteroids before, during & after the stressful situation is indicated.

• Adrenocortical Insufficiency Drug induced secondary adrenocortical insufficiency may result from too rapid withdrawal of corticosteroids and may be minimised by gradual reduction of dosage.

• Infection Corticosteroids may mask some signs of infection (such as fever and inflammation), and new infections may appear during their use.

• There may be decreased resistance and inability to localise infection when corticosteroids are used.

• Ophthalmological Complications Prolonged use of corticosteroids may produce posterior subcapsular cataracts or glaucoma with possible damage to optic nerves, and may enhance the establishment of secondary ocular infections dueto fungi or viruses.

• Children who are on immunosuppressant drugs are more susceptible to infections than healthy children. Chickenpox and measles, for example, can have a more serious or even fatal course in children on immunosuppressant corticosteroids. In such children, or in adults who have not had these diseases,

particular care should be taken to avoid exposure.

• If exposed, therapy with varicella zoster immune globulin (VZIG) or pooled intravenous immunoglobulin (IVIG), as appropriate, may be indicated. If chickenpox develops, treatment with antiviral agents may be considered.

4.5 Interaction with other medicinal products and other forms of interaction

• Moxifloxacin

No specific interaction studies have been performed with Moxifloxacin Ophthalmic Solution USP eye drops, solution. Given the low systemic concentration of Moxifloxacin following topical ocular administration of the medicinal product, drug interactions are unlikely to occur.

• Dexamethasone

The risk of increased intraocular pressure associated with prolonged corticosteroid therapy may

be more likely to occur with concomitant use of anti-cholinergic, especially atropine and related compounds, in patients predisposed to acute angle closure. The risk of corneal deposits or corneal opacity may be more likely to occur in patients presenting with compromised cornea and receiving polypharmacy with other phosphate containing eye medications. The following drug interactions are possible, but are unlikely to be of clinical significance, following the use of Dexamethasone: The therapeutic efficacy of dexamethasone may be reduced by phenytoin, phenobarbitone, ephedrine and rifampicin.

Glucocorticoids may increase the need for salicylates as plasma salicylate clearance is increased. If more than one topical ophthalmic medicinal product is being used, the medicines must be administered at least 5 minutes apart. Eye ointments should be administered last.

4.6 Fertility, pregnancy and lactation

It is not recommended during pregnancy.

4.7 Effects on ability to drive and use machines

Patients should be cautioned against engaging in activities requiring complete mental alertness, and motor coordination such as operating machinery until their response to eye drops is known.

4.8 Undesirable effects

In clinical trials the most frequently reported ocular adverse events were: decreased visual acuity, dry eye, keratitis, ocular discomfort, ocular hyperaemia, ocular pain, ocular pruritus, subconjunctival haemorrhage, and tearing. These events occurred in approximately 1-6% of patients.

Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org.

4.9 Overdose

There is limited experience of overdose with eye drops. Initiate general symptomatic and supportive measures in all cases of overdosages where necessary.

5. Pharmacological properties

5.1 Pharmacodynamic properties

- Moxifloxacin

Moxifloxacin is a quinolone/fluoroquinolone antibiotic. Moxifloxacin can be used to treat infections caused by the following bacteria: Aerobic Gram-positive microorganisms: Corynebacterium species, Micrococcus luteus, Staphylococcus aureus, Staphylococcus epidermidis, Staphylococcus haemolyticus, Staphylococcus hominis, Staphylococcus warneri, Streptococcus pneumoniae, and Streptococcus viridans group. Aerobic Gram-negative microorganisms: Acinetobacter lwoffii, Haemophilus influenzae, and Haemophilus parainfluenzae. Other microorganisms: Chlamydia trachomatis.

Moxifloxacin is bactericidal and its mode of action depends on blocking of bacterial DNA replication by binding itself to an enzyme called DNA gyrase, which allows the untwisting required to replicate one DNA double helix into two. Notably the drug has 100 times higher affinity for bacterial DNA gyrase than for mammalian. Moxifloxacin is a broad-spectrum antibiotic that is active against both Gram-positive and Gram-negative bacteria.

- Dexamethasone

Dexamethasone and its derivatives, dexamethasone sodium phosphate and dexamethasone acetate, are synthetic glucocorticoids. Used for its anti-inflammatory or immunosuppressive properties and ability to penetrate the CNS, dexamethasone is used alone to manage cerebral edema and with tobramycin to treat corticosteroid-responsive inflammatory ocular conditions.

5.2 Pharmacokinetic properties

- Moxifloxacin

Following topical ocular administration of Moxifloxacin Ophthalmic Solution USP, Moxifloxacin was absorbed into the systemic circulation. Plasma concentrations of Moxifloxacin were measured in 21 male and female subjects who received bilateral topical ocular doses of the medicinal product 3 times a day for 4 days. The mean steady-state Cmax and AUC were 2.7 ng/ml and 41.9 ng·hr/ml, respectively. These exposure values are approximately 1,600 and 1,200 times 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 in extended paediatric therapy. Up to 90% of dexamethasone is absorbed when given by mouth; peak plasma levels are reached between 1 and 2 hours after ingestion and show wide individual variations.

Distribution

Tissue distribution studies in animals show a high uptake of dexamethasone by the liver, kidney and adrenal glands; a volume of distribution has been quoted as 0.58 l/kg. In man, over 60% of circulating steroids are excreted in the urine within 24 hours, largely as unconjugated steroid.

Metabolism

Dexamethasone sodium phosphate is rapidly converted to dexamethasone within the circulation. Up to 77% of dexamethasone is bound to plasma proteins, mainly albumin. This percentage, unlike cortisol, remains practically unchanged with increasing steroid concentrations. The mean plasma half-life of dexamethasone is 3.6 ± 0.9h.

Distribution

Dexamethasone also appears to be cleared more rapidly from the circulation of the foetus and neonate than in the mother; plasma dexamethasone levels in the foetus and the mother have been found in the ratio of 0.32:1.

5.3 Preclinical safety data

Not Applicable

6. Pharmaceutical particulars

6.1 List of excipients

Benzalkonium Chloride Solution

Boric acid

Sodium Borate

Sodium Chloride

Hydrochloric acid

Sodium Hydroxide Pellets (Inj.)

Water for Injection

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 Months

Use the solution within one month after opening the container.

6.4 Special precautions for storage

Do not store above 30°C. Protect from direct sunlight.

6.5 Nature and contents of container

5 ml LDPE bottle in a carton along with insert.

6.6 Special precautions for disposal and other handling

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

7.1 Manufacturer:

THETA PHARMACEUTICALS LIMITED

D-42, IIE SIDCUL, SELAQUI, DEHRADUN-248011,

UTTARAKHAND, INDIA

7.2 Marketing Authorization Holder:

DAWA LIMITED

PLOT NO. 7879/8, BABA DOGO ROAD,

P. O. BOX 16633-00620, NAIROBI, KENYA.

8. Marketing Authorization Number:

CTD 12641

9. Date of first Authorization /renewal of the authorization:

November 2025

10. Date of revision of text:

20/11/2025

11. Dosimetry (if applicable)

N/A

12. Instructions for preparation of radiopharmaceuticals:

Not applicable