



# CORAL LABORATORIES LTD

ISO 9001:2008 Certificate No. IN015692

**1. Name of the medicinal product:**

**1.1 Name of the medicinal product :**

**OCUDEX EYE DROPS**

(Dexamethasone Sodium Phosphate Ophthalmic Solution USP 0.1 % w/v)

**1.2 Strength :**

Dexamethasone Sodium Phosphate USP Equivalent to  
Dexamethasone Phosphate 0.1 % w/v

**1.3 Pharmaceutical form:**

Eye Drops

**2. Qualitative and quantitative composition**

Each ml contains:

Dexamethasone Sodium Phosphate USP  
Equivalent to Dexamethasone Phosphate 0.1 % w/v  
Hydroxypropyl Methyl Cellulose BP 0.3 % w/v  
Water for injections USP q.s.  
Phenylmercuric Nitrate USP 0.001 % w/v

**Qualitative declaration:**

Dexamethasone Sodium Phosphate USP  
Equivalent to Dexamethasone Phosphate  
Hydroxypropyl Methyl Cellulose BP  
Water for injections USP  
Phenylmercuric Nitrate USP

**Quantitative declaration:**

Dexamethasone Sodium Phosphate USP  
Equivalent to Dexamethasone Phosphate 0.1 % w/v  
Hydroxypropyl Methyl Cellulose BP 0.3 % w/v  
Water for injections USP q.s.



**PRODUCT : OCUDEX EYE DROPS (Dexamethasone Sodium Phosphate Ophthalmic Solution USP 0.1 % w/v)**

**MODULE I : ADMINISTRATIVE INFORMATION**

**COUNTRY : NIGERIA**



Phenylmercuric Nitrate USP (0.001 % W/V)

**3. Pharmaceutical form**

Eye Drops

**4. Clinical particulars:**

**4.1 Therapeutic indications:**

Non-infected, steroid responsive, inflammatory conditions of the eye.

**4.2 Posology and method of administration**

**Posology**

Administer 1 drop 3-5 times daily into the conjunctival sac

Acute cases: up to 1 drop hourly

**Method of administration**

For local administration to the eye.

**4.3 Contraindications**

Use is contra-indicated in herpes simplex and other viral diseases of the cornea and conjunctiva, fungal disease, ocular tuberculosis, untreated purulent infections and hypersensitivity to any component of the preparation.

In children, long-term, continuous corticosteroid therapy should be avoided due to possible adrenal suppression.

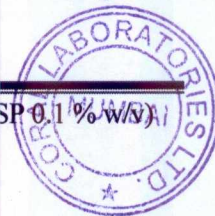
Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

**4.4 Special warnings and precautions for use**

Care should be taken to ensure that the eye is not infected before Minims Dexamethasone sodium phosphate 0.1% w/v Eye Drops, solution is used.

These drops should be used cautiously in patients with glaucoma and should be considered carefully in patients with a family history of this disease.

This medicinal product contains phosphates which may lead to corneal deposits or corneal opacity when topically administered. It should be used with caution in patients presenting with





compromised cornea and in instances where the patient is receiving polypharmacy with other phosphate containing eye medications (*see section 4.5*).

Topical corticosteroids should not be used for longer than one week except under ophthalmic supervision, as prolonged application to the eye of preparations containing corticosteroids has caused increased intraocular pressure. The dose of anti-glaucoma medication may need to be adjusted in these patients. Prolonged use may also increase the hazard of secondary ocular infections.

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 progressively discontinued.

Contact lenses should not be worn during treatment with corticosteroid eye drops due to increased risk of infection.

Systemic absorption may be reduced by compressing the lacrimal sac at the medial canthus for a minute during and following the instillation of the drops. (This blocks the passage of drops via the naso-lacrimal duct to the wide absorptive area of the nasal and pharyngeal mucosa. It is especially advisable in children.)

#### 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, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

The risk of increased intraocular pressure associated with prolonged corticosteroid therapy may be more likely to occur with concomitant use of anticholinergics, 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 Minims Dexamethasone sodium phosphate 0.1% w/v Eye Drops, solution in the eye:

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.

CYP3A4 inhibitors (including ritonavir and cobicistat): may decrease dexamethasone clearance resulting in increased effects and adrenal suppression/Cushing's syndrome. The combination should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid effects.

#### **4.6 Pregnancy and lactation**

Topically applied steroids can be absorbed systemically and have been shown to cause abnormalities of foetal development in pregnant animals. Although the relevance of this finding to human beings has not been established, the use of Minims Dexamethasone sodium phosphate 0.1% w/v Eye Drops, solution during pregnancy should be avoided.

Topically applied dexamethasone is not recommended in breastfeeding mothers, as it is possible that traces of dexamethasone may enter the breast milk.

#### **4.7 Effects on ability to drive and use machines:**

Instillation of this eye drop may cause transient blurring of vision. Warn patients not to drive or operate hazardous machinery until vision is clear.

#### **4.8 Undesirable effects:**

##### Eye disorders

Administration of Minims Dexamethasone sodium phosphate 0.1% w/v Eye Drops, solution to the eye may rarely cause stinging, burning, redness or watering of the eyes.

Prolonged treatment with corticosteroids in high dosage is, rarely, associated with sub-capsular cataract. In diseases which cause thinning of the cornea or sclera, perforations of the globe have been known to occur. In addition, optic nerve damage and visual acuity and field defects may arise following long term use of this product.

Not known: vision, blurred (see also section 4.4)



**PRODUCT : OCUDEx EYE DROPS (Dexamethasone Sodium Phosphate Ophthalmic Solution USP 0.1% w/v)**

**MODULE I : ADMINISTRATIVE INFORMATION**

**COUNTRY : NIGERIA**



### Endocrine disorders

Cushing's syndrome, adrenal suppression may occur due to the use of ocular dexamethasone (see section 4.4). The frequency of these adverse reactions is not known.

The systemic effects of corticosteroids are possible with excessive use of steroid eye drops.

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.

### **4.9 Overdose:**

As Minims are single-dose units, overdose is unlikely to occur.

## **5. Pharmacological properties:**

### **5.1 Pharmacodynamic properties:**

Pharmacotherapeutic group: Corticosteroids/ antiinfectives/ mydriatics in combination,

ATC code: S01CB01

Mechanism of action

Dexamethasone is a highly potent and long-acting glucocorticoid. It has an approximately 7 times greater anti-inflammatory potency than prednisolone, another commonly prescribed corticosteroid.

The actions of corticosteroids are mediated by the 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 will 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, the T lymphocytes being affected to a greater degree than the B lymphocytes. Lymphokine production is reduced, as is the sensitivity of macrophages to activation by lymphokines. Corticosteroids also retard epithelial regeneration, diminish post-inflammatory neo-vascularisation and reduce towards normal levels the excessive permeability of inflamed capillaries.

The actions of corticosteroids described above are exhibited by Minims Dexamethasone sodium phosphate 0.1% w/v Eye Drops, solution and they all contribute to its anti-inflammatory effect.

### **5.2 Pharmacokinetic Properties**



**PRODUCT : OCUDEX EYE DROPS (Dexamethasone Sodium Phosphate Ophthalmic Solution USP 0.1% w/v)**

**MODULE I : ADMINISTRATIVE INFORMATION**

**COUNTRY : NIGERIA**



**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.

**Biotransformation**

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  $3.6 \pm 0.9$ h.

**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.

**Elimination**

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**

The use of corticosteroids, including Minims Dexamethasone sodium phosphate 0.1% w/v Eye Drops, solution and its derivatives, in ophthalmology is well established. Little relevant toxicology has been reported, however, the breadth of clinical experience confirms its suitability as a topical ophthalmic agent.

**6. Pharmaceutical particulars**

**6.1 List of excipients**

Sr. No.	Ingredient	Specification
1.	Phenylmercuric Nitrate	USP
2.	Hydroxypropyl Methylcellulose	BP
3.	Water for Injection	USP





# **CORAL LABORATORIES LTD**

ISO 9001:2008 Certificate No. IN015692

## **6.2 Incompatibilities**

None

## **6.3 Shelf life**

24 months (2 Years) from date of manufacturing

## **6.4 Special precautions for storage**

Store at room temperature below 15°C to 25°C in a well closed container.

Protect from excess heat, light and moisture

Keep medicines out of reach of children.

## **6.5 Nature and contents of container**

A carton containing 5 ml LDPE white bottle with white cap along with pack insert.

## **6.6 Special precautions for disposal :**

None

## **7. Registrant :**

**NOMEDI PHARMACEUTICALS LTD**

387, Agege Motor Road, Mushin, P.O. Box 11623, Ilkeja, Lagos, Nigeria.

## **8. MANUFACTURER**

**CORAL LABORATORIES LTD.**

At, 5, 6 Khokhani Industrial Complex No.2,

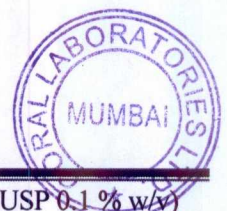
Near Sai Temple, Sativali, Vasai (East),

Dist : Thane 401 208. INDIA

Tel.: 25005245/ 5246 / 8208

Email: [exports@corallab.com](mailto:exports@corallab.com)

## **9. Date of revision of the text: NA**



**PRODUCT : OCUDEX EYE DROPS (Dexamethasone Sodium Phosphate Ophthalmic Solution USP 0.1 % w/v)**

**MODULE I : ADMINISTRATIVE INFORMATION**

**COUNTRY : NIGERIA**