SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Trade name:
Ivydexone Eye Drops

International non-proprietary name *(INN):*
Dexamethasone phosphate.

Strength
Dexamethasone Sodium Phosphate BP equivalent to Dexamethasone Phosphate 0.1% w/v

Each ml contains Dexamethasone phosphate as Dexamethasone sodium phosphate B.P 1 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains Dexamethasone phosphate as Dexamethasone sodium phosphate B.P 1 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye drops

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Ivydexone Eye Drops are used in the non-infectious forms of conjunctivitis, keratitis and blepharitis especially of allergic origin.

4.2 Posology and method of administration

The normal dosage is one drop to be put in the affected eye 3-5 times a day or more frequently as advised by your doctor. Do not touch your eye with the dropper on the bottle as this may contaminate the drops.

Posology

Adults and the elderly

One or two drops should be applied topically to the eye up to six times a day. *Note:* In severe conditions the treatment may be initiated with 1 or 2 drops every hour, the dosage should then be gradually reduced as the inflammation subsides.

Paediatric population

At the discretion of the physician.

Method of administration

For ocular use.

4.3 Contraindications.

Use is contraindicated in cases of:
• Hypersensitivity to the active substance or to any component of the preparation.
• Epithelial herpes simplex keratitis.
• Vaccinia, varicella or other viral infection of cornea and conjunctiva.
• Fungal diseases of ocular structures
• Mycobacterial ocular infections
• In children, long-term, continuous corticosteroid therapy should be avoided due to possible adrenal suppression

4.4 Special warnings and precaution for use

In some circumstances this medicine may not be suitable for you and your doctor may wish to give you a different medicine, so:
• If you are pregnant or intending to become pregnant
• If you are breast feeding a baby•
If you ever had to stop taking medicine because you were allergic to it
Do not wear soft contact lenses whilst using Ivydexone Eye Drops as the preservative may damage the lens.

Care should be taken to ensure that the eye is not infected before 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 10 days except under ophthalmic supervision, as prolonged application to the eye of preparations containing corticosteroids has caused increased intraocular pressure and corneal damage. 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. Fungal infections of the cornea may occur under long-term local corticosteroid treatment. Therefore, in case of persistent corneal ulcers, the possibility of a fungal infection

under corticoid treatment should be considered. If suspicion is present, samples should be taken. If symptoms do not improve within 2 days, a discontinuation of corticosteroid therapy should be considered.

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.

As any other corticosteroid, dexamethasone may affect the body's immune defence due to its protein catabolic nature and thus increase the hazard of secondary ocular infections. In these cases, treatment with dexamethasone should be discontinued until the infection is controlled effectively by an antibiotic therapy unless inflammation has been so violent that an anti-inflammatory treatment is mandatory

4.5 Interactions 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.

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.

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 this product during pregnancy should be avoided. Topically applied dexamethasone is not recommended in breastfeeding mothers, as it is possible that traces of the dexamethasone may enter the breast milk.

Fertility

Studies have not been performed to evaluate the effect of topical administration of dexamethasone on human fertility. There is limited clinical data to evaluate the effect of dexamethasone on male or female fertility.

Pregnancy

There are no adequate or well-controlled studies in pregnant women.

Synthetic glucocorticoids such as dexamethasone are generally less inactivated in the placenta than endogenous cortisol (=hydrocortisone) and therefore might pose a risk to the fetus.

Long-term treatment with glucocorticoids during pregnancy may retard intrauterine growth of the foetus.

If glucocorticoids are administered at the end of a pregnancy, there is a risk of atrophy of the foetal adrenal cortex which may require a gradual replacement therapy in the newborn.

Studies in animals have shown reproductive toxicity including formation of cleft palates (*see section 5.3 Preclinical safety data*).

Furthermore, epidemiological studies in connection with animal experiments indicated an association between prenatal exposure to glucocorticoids and an increased risk of metabolic and cardiovascular diseases during adulthood.

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Since a relevant systemic exposure cannot be excluded even after use of glucocorticoids in the eye, the use of dexamethasone should be avoided during pregnancy.

Minims Dexamethasone sodium phosphate 0.1% w/v Eye Drops, solution should not be used during pregnancy unless the clinical condition of the woman requires treatment with dexamethasone. If administration of dexamethasone is clearly necessary, it should be applied at the lowest possible dose for the shortest time period.

Breastfeeding

There is insufficient information on the excretion of dexamethasone/metabolites in human milk. A risk to the suckling newborns/infants cannot be excluded.

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

A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Minims Dexamethasone sodium phosphate 0.1% w/v Eye Drops, solution therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

It should only be used during lactation if clearly necessary. If higher doses are required for severe inflammation, breastfeeding must be stopped.

4.7 Effects on ability to drive and use machines

Installation 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

- You may experience a slight local burning sensation,
- Discomfort or itching.
- **Tabulated list of adverse reactions**
- Adverse reactions are listed by system organ class and frequency. The following convention has been used for the classification of frequencies: 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); Not known (cannot be estimated from the available data).

MedDRA SOC	Adverse reaction (s)	Frequency
Infections and infestations	Infection masked Secondary infection	Not known Not known
Immune system disorders	Hypersensitivity	Not known
Endocrine disorders	Adrenal suppression Cushing's syndrome	Not known Not known
Eye disorders	Cataract (with long-term use) Cataract subcapsular Eye irritation	Not known Rare Not known

	Eyelid ptosis Eye pain Keratitis Lacrimation increased Mydriasis Ocular hyperaemia Ulcerative keratitis Vision blurred Visual acuity reduced Eye stinging Eye burning	Not known Not known Not known Rare Not known Rare Not known Not known Not known Rare Rare
General disorders and administration site complications	Impaired healing	Not known
Investigations	Blood glucose increased (in diabetics) Intraocular pressure increased (with long term use)	Not known Not known
Injury, poisoning and procedural complications	**Open globe injury** **Optic nerve injury**	**Not known** **Not known**

- *Note*: Fungal infections of the cornea may occur under long-term topical corticosteroid treatment. Therefore, in case of persistent corneal ulcers, the possibility of a fungal infection under corticoid treatment should be considered. If suspicion is present, samples should be taken. If symptoms do not improve within 2 days, a discontinuation of corticosteroid therapy should be considered.
- 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: Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose.

This product is a single dose unit therefore overdose is unlikely to occur.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Dexamethasone is a highly potent and long acting-glucocorticoid. It has an approximately seven times greater anti-inflammatory potency than prednisolone. The actions of corticosteroids are mediated by the binding of the corticosteroid molecules to receptor molecules located within sensitive cells. Corticosteroids receptors are present in human trabecular meshwork cells and in rabbit iris ciliary body tissues. Corticosteroids will inhibit phosphate 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.

- **ATC CODE:** S01BA01

5.2 Pharmacokinetic properties

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 ± 0.9h.

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 Dexamethasone sodium phosphate 0.1 % w/v Eye drops 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

- Benzalkonium chloride
- Sodium metabisulphite
- Edetate Disodium
- Sodium phosphate dibasic
- Sodium phosphate monobasic
- Creatinine

6.2 incompatibilities

Not applicable.

6.3 shelf-life

24 months.

6.4 Special precautions for storage

• Store below 30°C, away from light.
• Discard any remaining solution one month after opening the bottle.
• Keep out of reach of children.

6.5 Nature and contents of container

5ml low density polyethylene bottles with a polypropylene spiked cap.

6.6 special precautions for disposal

No special precautions are required.

7. Market Authorization Holder and Manufacturing site address

Market authorization Holder

B. BRAUN PHARMACEUTICALS EPZ LTD.
L.R. No. 18474/84, Athi River
P.O. Box 51200-00100Nairobi, Kenya

Manufacturing site address
B. BRAUN PHARMACEUTICALS EPZ LTD.
L.R. No. 18474/84, Athi River
P.O. Box 51200-00100Nairobi, Kenya

8. Market authorization number

H99/328

9. Date of first registration

14/10/1999

10. Date of revision of the text

06/05/2026

11. Dosimetry

Not Applicable

12. Instructions for Preparation of Radiopharmaceuticals

Not Applicable