

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Dexamethason GALEN 1 mg/ml oogdruppels, oplossing in verpakking voor eenmalig gebruik

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml solution contains 1 mg of dexamethasone phosphate as dexamethasone sodium phosphate.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye drops, solution in single-dose container
Clear and colourless solution.

pH: 7.5 – 7.9

Osmolality: 240 – 280 mosmol/kg

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For treatment of non-infectious inflammatory conditions affecting the anterior segment of the eye.

4.2 Posology and method of administration

[Invented name] 1mg/ml eye drops, solution in single-dose container is for ocular use only.

This product should be used only under close ophthalmic supervision.

Posology

The usual posology is of 1 drop 4 to 6 times daily in the affected eye.

In severe cases, treatment may be started with 1 drop every hour but dosage should be reduced to one drop every 4 hours when favourable response is observed. Gradual tapering off is recommended in order to avoid a relapse.

The duration of treatment will generally vary from a few days to a maximum of 14 days.

Elderly patients

There has been wide experience with the use of dexamethasone eye drops in elderly patients. The dosage recommendations given above reflect the clinical data derived from this experience.

Paediatric population

Efficacy and safety has not been established in the paediatric population.

In children, long-term continuous corticosteroid therapy should be avoided due to possible adrenal suppression (see section 4.4).

Method of administration

[Invented name] is a sterile solution that does not contain a preservative. The solution from one individual single-dose container is to be used immediately after opening for administration to the affected eye(s). For single-use only: since sterility cannot be maintained after the individual single-dose container is opened, any remaining contents must be discarded immediately after administration.

Patients should be instructed:

- to wash their hands carefully prior to instillation,
- to twist off the cap and to avoid contact between the tip of the dispenser and the eye or eyelids,
- to throw away the single-dose container after use.

Nasolacrimal occlusion by compression of lacrimal ducts may reduce systemic absorption.

4.3 Contraindications

- Eye infections not controlled by anti-infectious treatment, such as:
 - Acute purulent bacterial infections including *Pseudomonas* and mycobacterial infections,
 - Fungal infections,
 - Epithelial Herpes simplex keratitis (dendritic keratitis), vaccinia, varicella zoster and most other viral infections of the cornea and conjunctiva,
 - Amoebic Keratitis,
- Perforation, ulceration and injury of cornea with uncompleted epithelialisation (see also section 4.4),
- Known glucocorticosteroid-induced ocular hypertension,
- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Topical steroids should never be given for an undiagnosed red eye.

Patients should be monitored at frequent intervals during treatment with dexamethasone eye drops. Prolonged use of corticosteroid treatment may result in ocular hypertension/glaucoma (especially for patients with previous IOP induced by steroids or with pre-existing high IOP or Glaucoma) and also cataract formation, especially in children and elderly population.

The use of corticosteroids may also result in opportunistic ocular infections due to the suppression of host response or to the delay of their healing. In addition, topical ocular corticosteroids may promote, aggravate or mask signs and symptoms of opportunistic eye infections.

Patients with an eye infection should only receive local steroid treatment when the infection has been controlled by an effective anti-infectious treatment. Such patients should be carefully and regularly monitored by an ophthalmologist.

In some particular inflammatory conditions such as epicleritis, NSAIDs are the first line treatment, Dexamethasone should be used only if NSAIDs are contra-indicated.

Patients with a corneal ulcer should generally not receive topical dexamethasone except when inflammation is the main cause of healing delay and when the appropriate aetiological treatment has already been prescribed. Such patients should be carefully and regularly monitored by an ophthalmologist.

Thinning of the cornea and sclera may increase the risk of perforations with the use of topical corticosteroids.

This medicine contains 2.32 milligrams phosphates in each milliliter. Corneal calcification requiring corneal graft surgery for visual rehabilitation has been reported for patients treated with ophthalmic preparations containing phosphates such as [Invented name]. At the first sign of corneal calcification the drug should be withdrawn and the patient should be switched to a phosphate-free preparation

Posterior subcapsular cataract might occur at cumulative doses of dexamethasone. Diabetics are also more prone to develop subcapsular cataracts following topical steroid administration.

The use of topical steroids in allergic conjunctivitis is only recommended for severe forms of allergic conjunctivitis not responding on standard therapy and only for a short period.

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.

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.

Wearing of contact lenses during treatment with corticosteroid eye drops should be avoided.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

In case of concomitant treatment with other eye drops, solution, instillations should be spaced out by 15 minutes.

Superficial stromal corneal precipitations of calcium phosphate have been reported under combined use of corticosteroids and topical beta-blockers.

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 Fertility, pregnancy and lactation

Pregnancy

Insufficient data are available on the use of [Invented name] in human pregnancy to assess possible harmful effects. Corticosteroids cross the placenta. Teratogenic effects have been observed in animals (see section 5.3). However, there is no evidence to date that teratogenic effects are induced in humans. After systemic use of corticosteroids, at higher doses, effects on the unborn/neonate (intrauterine growth inhibition, inhibition of the function of the adrenal cortex) have been reported. However, these effects have not been reported for ocular use.

As a precautionary measure, it is preferable to avoid the use of [Invented name] during pregnancy.

Breastfeeding

It is not known whether this medicine is excreted in breast milk. However, the total dose of dexamethasone is low.

[Invented name] can be used during lactation.

Fertility

There are no data on potential effects of Dexamethasone 1 mg/ml on fertility.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

As with any eye drops, temporarily blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs, the patient must wait until the vision is clear before driving or using machines.

4.8 Undesirable effects

Endocrine disorders:	
Not known (cannot be estimated from the available data):	Cushing's syndrome, Adrenal suppression* (see section 4.4)
Eye disorders:	
Very common ($\geq 1/10$):	Increase of the intra-ocular pressure*.
Common ($\geq 1/100$ to $< 1/10$):	Discomfort*, irritation*, burning*, stinging*, itching* and blurred vision (see also section 4.4)*
Uncommon ($\geq 1/1,000$ to $< 1/100$):	Allergic and hypersensitivity reactions, delayed wound healing, posterior capsular cataract*, opportunistic infections, glaucoma*.
Very rare ($< 1/10,000$, including isolated reports):	Conjunctivitis, mydriasis, facial oedema, ptosis, corticosteroid-induced uveitis, corneal calcifications, crystalline keratopathy, changes in corneal thickness*, corneal oedema, corneal ulceration and corneal perforation.

* see section *Description of selected adverse reactions*

Description of selected adverse reactions

Increase of the intra-ocular pressure, glaucoma and cataract may occur. Prolonged use of corticosteroid treatment may result in ocular hypertension/glaucoma (especially for patient with previous IOP induced by steroids or with pre-existing high IOP or Glaucoma) and also cataract formation. Children and elderly patients may be particularly susceptible to steroid-induced IOP rise (see section, 4.4).

Increase of the intra-ocular pressure induced by corticosteroid topical treatment has been generally observed within 2 weeks of treatment (see section 4.4.).

Diabetics are also more prone to develop subcapsular cataracts following topical steroid administration.

Discomfort, irritation, burning, stinging, itching and blurred vision frequently may occur immediately after instillation. These events are usually mild and transient and have no consequences.

In diseases causing thinning of the cornea, topical use of steroids could lead to perforation in some cases (see section 4.4).

Depression of adrenal function associated with systemic absorption of the product may occur when the instillations are administered with a frequent dosing schedule (see also sections 4.2 and 4.4).

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

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 via the national reporting system listed in [Appendix V](#).

4.9 Overdose

In the case of topical overdosage, the treatment should be stopped. In case of prolonged irritation, the eye(s) should be rinsed with sterile water.

The symptomatology due to accidental ingestion is not known. As with other corticosteroids however, the physician may consider gastric lavage or emesis.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: OPHTALMOLOGICALS, ANTIINFLAMMATORY AGENTS, Corticosteroids, plain, ATC code: S01B A01

Dexamethasone sodium phosphate is a hydrosoluble inorganic ester of dexamethasone. It is a synthetic corticosteroid with an anti-inflammatory and anti-allergic action. Dexamethasone has more potent anti-inflammatory action compared to hydrocortisone (approximately 25:1) and prednisolone (approximately 5:1).

5.2 Pharmacokinetic properties

Due to its hydrophilic properties, dexamethasone sodium phosphate is barely absorbed by the intact epithelium of the cornea.

Following absorption via the eye and the nasal mucosa, dexamethasone sodium phosphate is hydrolyzed in the system to dexamethasone.

Afterwards, dexamethasone and its metabolites are mainly eliminated via the kidneys.

5.3 Preclinical safety data

Mutagenic and tumorigenic potential

Present findings yield no indications of clinically relevant genotoxic properties of glucocorticoids.

Reproductive toxicity

In animal studies, oral corticosteroids have been associated with foetal resorptions and cleft palate at doses starting from 8.3 mg/kg/day for 30 days. In rabbits, intramuscular administration (10 mg/kg for 4 days) induced foetal resorptions and multiple malformations involving the head, ears, limbs, and palate. Additional findings include intrauterine growth restriction and alterations in the functional development of the central nervous system.

In mice and rabbits, ocular dexamethasone at 0.15% induced cleft palate, while abnormalities of the sexual organs were reported at higher doses.

In humans, oral dexamethasone is administered during pregnancy to accelerate fetal lung maturation and for the prenatal treatment of congenital adrenal hyperplasia (CAH). The risk of major congenital malformations, such as oral clefts, in children exposed in utero to corticosteroids is considered not statistically different from that of the general population.

Following ocular administration of 0.1% dexamethasone, blood concentrations of about 0.7 ng/ml have been measured, approximately 50–100 times lower than the C_{max} observed after a 5 mg oral

dose, indicating a wide safety margin. Nevertheless, in consideration of the scarcity of data in humans, the use of corticosteroids with lower potency may be preferable during pregnancy.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium edetate
Disodium phosphate dodecahydrate
Sodium chloride
Water for injections

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

After first opening of the pouch: use the single-dose containers within 28 days.

After opening of the single-dose container: use immediately and discard the single-dose container after use.

6.4 Special precautions for storage

Keep the single-dose containers in the pouch, in order to protect from light.

6.5 Nature and contents of container

0.4 ml in single-dose low density polyethylene container packed in pouches; box of 10, 20, 30, 50 or of 100 single-dose containers.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER

GALENpharma GmbH
Wittland 13
24109 Kiel
Duitsland

8. MARKETING AUTHORISATION NUMBER(S)

RVG 134359

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Datum van eerste verlening van de vergunning: 6 mei 2026

10. DATE OF REVISION OF THE TEXT