

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS:** S4**DEXAGEL Eye Gel****Dexamethasone Sodium Phosphate****Read all of this leaflet carefully before you start using DEXAGEL**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- DEXAGEL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What DEXAGEL is and what it is used for
2. What you need to know before you use DEXAGEL
3. How to use DEXAGEL
4. Possible side effects
5. How to store DEXAGEL
6. Contents of the pack and other information

1. What DEXAGEL is and what it is used for

DEXAGEL is an eye gel which contains a substance called dexamethasone. This substance is a corticosteroid which inhibits inflammatory symptoms.

DEXAGEL is indicated to reduce ocular inflammation after cataract surgery.

2. What you need to know before you use DEXAGEL

Do not use DEXAGEL:

- if you are hypersensitive (allergic) to dexamethasone or any of the other ingredients of DEXAGEL (listed in section 6)
- if you are suffering from an ocular infection which could be bacterial (acute purulent infection) fungal, or viral (e.g. herpetic virus)
- if you have ocular tuberculosis
- if you have glaucoma
- if you have had previous ocular hypertension induced by corticosteroid treatment
- if you have corneal damages (perforation, ulcerations or lesions associated with incomplete healing).

Warnings and precautions

Talk to your doctor or pharmacist before using DEXAGEL.

Close ophthalmic monitoring is required during the use of DEXAGEL. Tell your doctor:

- if you are an elderly person (e.g. over 65 years of age), as more frequent ophthalmic monitoring is recommended.

- if you have an ocular infection.
- if you have a history of herpetic disease (disease caused by the herpes simplex virus, e.g. cold sores or genital herpes).
- if you are suffering from a corneal ulcer.
- if you suffer from increased intraocular pressure (glaucoma).
- if you have already experienced adverse reactions to local steroids treatment.
- if you suffer from diabetes.

Contact your doctor if you experience blurred vision or other visual disturbances.

Talk to your doctor if you experience swelling and weight gain around the trunk and in the face as these are usually the first manifestations of a syndrome called Cushing's syndrome.

Severe allergic conjunctivitis: if you have severe allergic conjunctivitis, tell your doctor.

Red eye: if you have a red eye, do not use DEXAGEL and tell your doctor.

Contact lenses: you should avoid wearing contact lenses during treatment with DEXAGEL.

Children and adolescents

The safety and efficacy in children have not been established.

Other medicines and DEXAGEL

Always tell your health care provider if you are using, or have recently used, any other medicine.

(This includes all complementary or traditional medicines).

- Tell your doctor if you are taking ritonavir or cobicistat (medicines for the treatment of HIV), as this may increase the amount of dexamethasone in the blood.

- Tell your doctor if you are taking any of the following medicines, as they may reduce the effect of DEXAGEL:
 - phenytoin (to treat epilepsy),
 - phenobarbitone (for the treatment of epilepsy or anxiety),
 - ephedrine (used to treat breathing problems, nasal congestion, low blood pressure problems, or myasthenia gravis),
 - rifampicin (medicine for the treatment of tuberculosis).
- DEXAGEL may increase the need for salicylates (aspirin), talk to your doctor if you are on treatment with aspirin.
- Talk to your doctor if you take anticholinergic medicines (e.g. atropine), you may be at greater risk of increased intraocular pressure.
- The use of topical steroids (like DEXAGEL) together with topical non-steroidal anti-inflammatories (NSAIDs) (e.g. diclofenac) may increase the potential for corneal healing problems.

If you are using any other medicine to be applied in the eye, you should wait 15 minutes between each application. DEXAGEL should be administered last.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using this medicine.

Pregnancy

There is insufficient information on the use of DEXAGEL during pregnancy. Therefore, the use of DEXAGEL should be avoided during pregnancy. If administration of DEXAGEL is clearly necessary, it should be applied at the lowest possible dose for the shortest time span.

Breastfeeding

There is no evidence of harm to the breastfeeding infant with ophthalmic use of dexamethasone. Nevertheless, DEXAGEL should only be used during breastfeeding if clearly necessary. If higher doses are required for severe inflammation, breastfeeding must be stopped.

Fertility

Studies have not been performed to evaluate the effect of DEXAGEL on human fertility.

Driving and using machines

Due to the gel formulation of DEXAGEL, temporary blurred vision may affect the ability to drive or use machines. Do not drive or use machines until normal vision has returned.

DEXAGEL contains benzododecinium chloride

This medicine contains a preservative, benzododecinium chloride (a C-12 homologue of benzalkonium chloride).

The preservative may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using DEXAGEL and put them back 15 minutes afterwards.

It may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using DEXAGEL, talk to your doctor.

3. How to use DEXAGEL

Do not share medicines prescribed for you with any other person.

Always use DEXAGEL exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is 1 drop every 4 hours. Later this can be reduced to 1 drop 3 to 4 times a day.

DEXAGEL should be used in your eye(s) only.

You should press lightly in the corner of your eye for a minute following the instillation of the gel. This reduces the systemic absorption of DEXAGEL.

Your doctor will tell you how long the treatment with DEXAGEL will last, but this should not exceed 4 weeks.

If you have the impression that the effect of X is too strong or too weak, tell your doctor or pharmacist.

If you use more DEXAGEL than you should

Rinse the eye with water if you have applied too much product to your eye and there is prolonged irritation.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use DEXAGEL

Do not use a double dose to make up for a forgotten dose.

4. Possible side effects

DEXAGEL can have side effects.

Not all side effects reported for DEXAGEL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using DEXAGEL, please consult your health care provider for advice.

If any of the following happens, stop using DEXAGEL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting

These are all very serious side effects. If you have them, you may have had a serious reaction to DEXAGEL. You may need urgent medical attention or hospitalisation.

DEXAGEL can have the following side effects in your eyes. Tell your doctor if you notice any of the following:

Frequent side effects

- cataract
- increased intraocular pressure (with long term use)

Less frequent side effects

- opportunistic infections
- conjunctivitis (inflammation of the eye membranes)
- corneal oedema
- corneal thinning
- eye irritation
- drooping eyelids (ptosis)
- eye itching (pruritus)
- foreign body sensation in the eye
- keratitis (inflammation of the cornea – the clear layer at the front of the eye)
- dilation of the pupil (mydriasis)
- ocular discomfort
- corneal deposits

Side effects with unknown frequency

- eye infection
- blurred vision

DEXAGEL can also have side effects that affect other parts of your body. Tell your doctor if you notice any of the following:

Less frequent side effects

- hypersensitivity (allergic reactions)
- facial oedema (swelling)

Side effects with unknown frequency

- adrenal suppression (which can result in hormone problems)
- Cushing's syndrome (swelling and weight gain of the body and face – *see section 2*)

Warnings and precautions

- increased blood glucose levels

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>

You can also report side effects directly to the company, using the following e-mail address:
PV-SouthAfrica@bausch.com

By reporting side effects, you can help provide more information on the safety of DEXAGEL.

5. How to store DEXAGEL

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Discard any remaining eye gel after 6 weeks of first opening the tube.
- Do not use after the expiry date stated on the tube or carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What DEXAGEL contains

- The active substance is dexamethasone sodium phosphate.
1 gram eye gel contains 0,985 mg of dexamethasone sodium phosphate. One drop corresponds to approximately 0,02 mg dexamethasone sodium phosphate.
- The other ingredients are benzododecinium chloride, carbomer, disodium edetate, sodium hydroxide, sorbitol, water for injection.

What DEXAGEL looks like and contents of the pack

DEXAGEL is a colourless, viscous, sterile gel.

It is provided in 5 g white polyfoil tubes with a white tube head and closed with a white screw cap.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

The Professional Information is available on the company website, www.bausch.co.za, or may be requested telephonically: +27 10 025 2100.