

DUCRESSA[®] 1mg/ml + 5mg/ml EYE DROPS SOLUTION

Dexamethasone/Levofloxacin

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What DUCRESSA is used for

Ducressa is an eye drops solution that contains levofloxacin and dexamethasone.

Ducressa is used to prevent and treat inflammation and prevent possible infection of the eye after cataract surgery in adults.

How DUCRESSA works

Levofloxacin is an antibiotic of the type called fluoroquinolones (sometimes shortened to quinolones). It works by killing some types of bacteria that can cause infections.

Dexamethasone is a corticosteroid, it has an anti-inflammatory action (stopping symptoms like pain, heat, swelling and redness).

Before you use DUCRESSA

- When you must not use it
- if you are allergic to levofloxacin (or other quinolones) or dexamethasone (or other corticosteroids) or any of the other ingredients of this medicine.
- if you are suffering from an eye infection that you are not using medicine for including viral (like herpes simplex keratitis or varicella), fungal infections and tuberculosis of the eye.

You could have an infection if you have a sticky discharge from your eye or if

you have a red eye that has not been seen by a doctor.

- Before you start use it

Talk to your doctor before using Ducressa:

- If you are using any other antibiotic treatment, including oral antibiotics. As with other anti-infectives, prolonged use may induce antibiotic resistance with the result of overgrowth of pathogenic microorganisms.
- If you suffer from high pressure in the eye or if you have already had high pressure in the eye after using an eye steroid medicine. You are at risk of having this again if you use Ducressa. If you suffer from high pressure in the eye tell your doctor.
- If you have glaucoma.
- If you have visual disturbance or blurred vision.
- If you are using ocular NSAIDs (Nonsteroidal Anti Inflammatory Drugs) see section "Other medicines and Ducressa."
- If you have a disorder causing a thinning of the eye tissues because prolonged steroid treatments may cause further thinning and possible perforation.
- If you are diabetic.

Ducressa is not recommended for children and adolescents below 18 years due to a lack of data on safety and efficacy in this age group.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine. Ducressa should not be used during pregnancy or breast-feeding.

Ducressa contains phosphate buffer. If you suffer from severe damage to the clear layer at the front of the eye (the cornea), phosphate may cause in very rare cases cloudy patches on the cornea due to calcium build-up during treatment. Talk with your doctor who

may prescribe you a phosphate-free treatment.

- Taking other medicines

Tell your doctor or pharmacist

- if you are using, have recently used or might use any other medicines, including medicines obtained without a prescription.
- if you are applying any other type of eye drop or eye ointment before you start to use Ducressa (see section 3 – How to use Ducressa).
- if you are using ocular NSAIDs (used against pain and inflammation in the eye) like ketorolac, diclofenac, bromfenac and nepafenac. Simultaneous use of ocular steroids and ocular NSAIDs may increase the potential for healing problems in your eye.
- if you are using ritonavir or cobicistat (used in HIV treatment), as these may increase the amount of dexamethasone in the blood.
- if you are using probenecid (to treat gout), cimetidine (to treat stomach ulcer) and cyclosporin (to prevent transplant rejection) as they may change absorption and metabolism of levofloxacin.

How to use DUCRESSA

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

- How much to use

The recommended dose is 1 drop in the affected eye every 6 hours. The maximum dose is 4 drops per day.

- When to use it

Every 6 hours, maximum four times a day.

- How long to use it

The usual total treatment course with Ducressa is 7 days. Your doctor will advise you how long to apply the drops.

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If you stop using this medicine earlier than instructed, tell your doctor. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

- If you forget to use it

If you forget to use this medicine, do not worry, just use it as soon as possible. Do not take a double dose to make up for a forgotten dose.

- If you use too much (overdose)

If you use more of this medicine than you should it can be washed out with warm water.

While you are using it

- Things you must do

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

- Things you must not do

This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

- Things to be careful of

After cataract surgery you should not wear contact lenses for the whole duration of therapy with Ducressa.

If you experience temporary blurred vision after using this medicine for a short time, you should not drive or operate machinery until your vision is clear.

If you are putting any other medicine in your eye, you should wait at least 15 minutes between applying the different types of drops. Eye ointments should be used last.

Ducressa contains benzalkonium chloride. Benzalkonium chloride 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 this medicine, talk to your doctor.

Wash carefully your hands before open the bottle. Take special care that the tip of the dropper bottle does not touch your eye, the skin around your eye or your fingers.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Most side effects are not serious and affect only the eye.

- Very rarely this medicine can cause severe allergic reactions (anaphylactic reactions), accompanied by swelling and tightness in the throat and breathing difficulties.
- Stop using Ducressa and contact your doctor immediately if any of these symptoms occurs.
- Tendon swelling and rupture have happened in people taking oral or intravenous fluoroquinolones, particularly in older patients and in those treated concurrently with corticosteroids. Stop taking Ducressa if you develop pain or swelling of the tendons (tendinitis).

You may also experience some or all of the following effects in your eye(s). The very common side effect is high pressure in the eye. The common side effects are eye discomfort, stinging or irritation of the eye, burning and itching in the eye, blurred or decreased vision and mucus in the eye.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers →

Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of DUCRESSA

- Storage

Store below 30°C.

Keep this medicine out of the sight and reach of children.

- Disposal

Do not use this medicine after the expiry date which is stated on the bottle label and carton after "EXP". The expiry date refers to the last day of that month.

Do not use this medicine if you notice that the plastic ring around the cap and neck is missing or broken before you start a new bottle.

Keep the bottle tightly closed. To prevent infections, you must throw away the bottle 28 days after you first opened it, and use a new bottle.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

- What it looks like

Ducressa is a clear, greenish-yellow solution practically free from particles, even if expelled drops appear clear and colourless. It is supplied in a pack containing one 5 ml white plastic bottle with white dropper. The plastic bottle is closed with a screw cap.

- Ingredients

- Active ingredient

Each millilitre of solution contains 5mg of levofloxacin and 1mg of dexamethasone. Levofloxacin as hemihydrate and dexamethasone as sodium phosphate.

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- Inactive ingredients

Monobasic sodium phosphate
monohydrate, disodium phosphate
dodecahydrate, sodium citrate,
benzalkonium chloride, sodium
hydroxide /hydrochloric acid (as pH
adjuster), water for injection.

- MAL number(s):

MAL23076003ACRZ

Manufacturer:

TUBILUX PHARMA S.p.A.

Via Costarica 20/22,
00071 Pomezia
(Roma) ITALY.

Product Registration Holder:

Santen Pharma Malaysia Sdn. Bhd.

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