Package leaflet: Information for the user
Ducressa 1 mg/ml + 5 mg/ml
eye drops solution

dexamethasone / levofloxacin

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- 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.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ducressa is and what it is used for

What kind of medicine is it and how does it work?
Ducressa is an eye drops solution that contains levofloxacin and dexamethasone.
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).

What is your medicine for?
Ducressa is used to prevent and treat inflammation and prevent possible infection of the eye after cataract surgery in adults.

2. What you need to know before you use Ducressa

Do not use Ducressa:
- if you are allergic to levofloxacin (or other quinolones) or dexamethasone (or other corsticosteroids) or any of the other ingredients of this medicine (listed in section 6).
- 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.

Warnings and precautions
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 microrganisms.
- 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.

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

Children and adolescents
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.

Other medicines and Ducressa
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.

Pregnancy and breast-feeding
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.

Driving and using machines
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.

Ducressa contains phosphate buffer
This medicine contains 4.01 mg phosphates per ml, corresponding to 0.12 mg per drop. 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.

Ducressa contains benzalkonium chloride
This medicine contains 0.05 mg benzalkonium chloride per ml corresponding to 0.0015 mg per drop.

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.

3. 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.

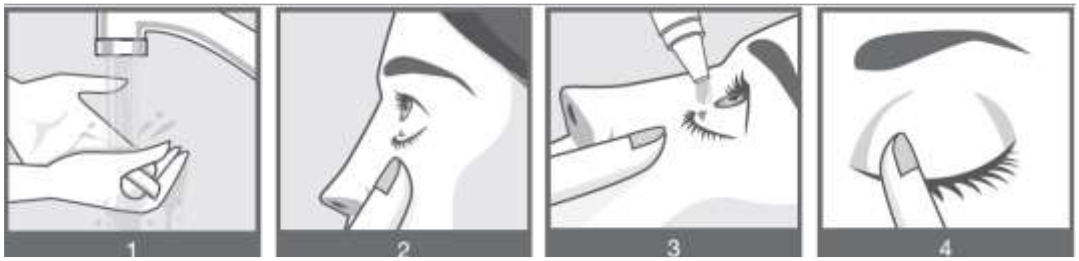
The recommended dose is 1 drop in the affected eye every 6 hours. The maximum dose is 4 drops per day. The usual total treatment course with Ducressa is 7 days, followed, if deemed necessary by the doctor, by another 7 days of steroid eye drops.

Your doctor will advise you how long to apply the drops.

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.

Instruction for use:
If possible, ask someone else to apply the drops for you. Ask them to read these instructions with you before applying the drops.

1) Wash carefully your hands (picture 1).
2) Open the bottle. **Remove the loose collar from the cap when the bottle is first opened.**
Take special care that the tip of the dropper bottle does not touch your eye, the skin around your eye or your fingers.
3) Twist off the bottle cap. Hold the bottle pointing down, between your thumb and fingers.
4) Pull down your lower eyelid with a finger, until there is a 'pocket' between the eyelid and your eye. The drop will go in here (picture 2).
5) Tilt your head back and bring the bottle tip close to the eye and squeeze the bottle gently in the middle and let a drop fall into your eye (picture 3). Please note that there might be a few seconds delay between squeezing and the drop coming out. Do not squeeze too hard.
6) After using Ducressa press a finger into the corner of your eye by the nose. This helps to stop the medicine getting into the rest of the body (picture 4).



If a drop misses your eye, try again. Put the bottle cap firmly back on immediately after use.

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

If you forget to use Ducressa
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 stop using Ducressa
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.

4. Possible 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):

Very common (may affect more than 1 in 10 people):
- high pressure in the eye.

Common (may affect up to 1 in 10 people):
- discomfort, stinging or irritation, burning, itching in the eye
- blurred or decreased vision
- mucus in the eye.

Uncommon (may affect up to 1 in 100 people):
- corneal healing which takes longer than expected
- eye infections
- abnormal sensation in the eye
- increased tearing
- dry and tired eye
- pain in the eye
- brighter vision
- swelling or redness (bloodshot eyes) of the front covering of the eye (conjunctivae)
- swelling or redness of the eyelid
- sensitivity to light
- sticky eyelids.

Very rare (may affect up to 1 in 10,000 people):
- increase in pupil size
- drooping eyelids
- setting of calcium on the surface of the eye (calcification of cornea)
- tears and a sandy sensation in your eye (crystalline keratopathy)
- change in the thickness of the surface of the eye
- ulcer on the surface of the eye
- small holes on the surface of the eye (perforation of the cornea)
- swelling of the surface of the eye (corneal oedema)
- inflammation of the eye which causes pain and redness (uveitis).

You may experience effects in other areas of your body including:

Uncommon (may affect up to 1 in 100 people):
- headache
- alteration of the taste
- pruritus
- stuffed or runny nose.

Rare (may affect up to 1 in 1,000 people):
- allergic reactions such as skin rash.

Very rare (may affect up to 1 in 10,000 people):
- facial swelling.

Unknown
- Reduction of adrenal gland function, which could be shown by low blood sugar, dehydration, weight loss and feeling confused about where you are.
- Hormone problems: growth of extra body hair (particularly in women), muscle weakness and wasting, purple stretch marks on body skin, increased blood pressure, irregular or missing periods, changes in the levels of protein and calcium in your body, stunted growth in children and teenagers and swelling and weight gain of the body and face (called Cushing's syndrome).

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom: Yellow Card Scheme: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
Ireland: HPRA Pharmacovigilance Website: www.hpra.ie.

5. How to store Ducressa

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

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.
This medicine doesn't require any special storage condition.

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.

6. Contents of the pack and other information

What Ducressa contains
- The active substances are levofloxacin as hemihydrate and dexamethasone as sodium phosphate. Each millilitre of solution contains 5 mg of levofloxacin and 1 mg of dexamethasone.
- The other ingredients are sodium dihydrogen phosphate monohydrate, disodium phosphate dodecahydrate, sodium citrate, benzalkonium chloride, sodium hydroxide/hydrochloric acid (as pH adjuster), water for injections.

What Ducressa looks like and contents of the pack
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.

Marketing Authorisation Holder
Santen Oy
Niittyhaankatu 20
33720 Tampere
Finland

Manufacturer responsible for batch release
Santen Oy
Kelloportinkatu 1
33100 Tampere
Finland

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:
Ducressa: Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom (Northern Ireland)

Dugressa: France

This leaflet was last revised in April 2022.

Detailed information on this medicine is available on the websites of the Medicines & Healthcare products Regulatory Agency (MHRA), www.mhra.gov.uk, and the Health Products Regulatory Authority (HPRA), www.hpra.ie.