1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

VOXIDEX 5 mg/1 mg per 1 ml eye drops

Levofloxacin and Dexamethasone

Read all of this leaflet carefully before you start using/are given VOXIDEX

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- VOXIDEX 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 VOXIDEX is and what it is used for
2. What you need to know before you use VOXIDEX
3. How to use VOXIDEX
4. Possible side effects
5. How to store VOXIDEX
6. Contents of the pack and other information

1. What VOXIDEX is and what it is used for

VOXIDEX is an eye drop 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). VOXIDEX 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 VOXIDEX

Do not use VOXIDEX:

- if you are hypersensitive (allergic) to levofloxacin (or to other quinolones) or dexamethasone (or to other corticosteroids) or any of the other ingredients of VOXIDEX (listed in section 6).
- if you are suffering from an eye infection that you are not using medicine for (including viral infections, 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

Special care should be taken with VOXIDEX:

- This medicine should not be used on a prolonged basis.

  The usual treatment course is 7 days, but your healthcare provider will re-evaluate you to assess the need to continue the administration of a corticosteroid eye drops on its own (see How to use VOXIDEX below).
- Cushing syndrome may occur after intensive or long-term continuous therapy with corticosteroid-containing products. This includes patients on ritonavir and cobicistat

(medicines used in the treatment of HIV). Signs of Cushing syndrome includes a fatty hump between the shoulders, a rounded face and pink or purple stretch marks.

- If you notice any signs of swelling or pain in the thick fibrous cords that attach muscle to bone (tendons).

Do not swallow or inject VOXIDEX.

Prolonged use (generally observed within 2 weeks of treatment) may result in secondary eye infections (bacterial, viral, or fungal). VOXIDEX may mask signs and symptoms of eye infections.

Children and adolescents

There is no experience with VOXIDEX in children younger than 18 years.

Other medicines and VOXIDEX

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following:

- Probenecid, used to treat gout.
- Cimetidine, used to treat ulcers in your digestive tract.
- Ciclosporin, used in patients who had an organ transplant.
- Other topical corticosteroids or Non-Steroidal-Anti-Inflammatory Drugs (NSAIDs) such as fluocinolone or diclofenac.

Pregnancy, breastfeeding and fertility

The safety of VOXIDEX in pregnancy and lactation has not been established.

VOXIDEX should not be used during pregnancy. Do not breastfeed your baby when using VOXIDEX.

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 healthcare provider for advice before using this medicine.

Driving and using machines

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 (see section 4).

VOXIDEX contains benzalkonium chloride

Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards. 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 VOXIDEX

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

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

The usual dose of VOXIDEX is 1 drop in the affected eye directly after surgery, then every 6 hours thereafter. The maximum dose is 4 drops/day.

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

Once you have completed one week of therapy with VOXIDEX, your treating healthcare provider will re-evaluate you to assess the need to continue the administration of corticosteroid eye drops on its own. The length of this treatment can depend on your risk factors and outcome of surgery and must be determined by the treating healthcare provider.

If you are putting any other medicine in your eye, you should wait at least 5 minutes between applying the different types of drops.

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

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 your hands carefully.

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) Tilt your head back (picture 1).

5) 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).

6) Bring the bottle tip close to the eye. Do this in front of a mirror if it helps.

7) Squeeze the bottle gently in the middle and let a drop fall into your eye.

Please note that there might be a few seconds delay between squeezing and the drop coming out.

Do not squeeze too hard.

8) After using VOXIDEX 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 3).



Picture 1



Picture 2



Picture 3

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

If you use more VOXIDEX than you should

If you use more VOXIDEX than you should it can be washed out with warm water.

If you forget to use VOXIDEX

If you forget to use VOXIDEX, administer the next drop as soon as possible. Do not use a double dose to make up for a forgotten dose.

If you stop using VOXIDEX

Do not discontinue therapy prematurely.

If you stop using VOXIDEX, 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

VOXIDEX can have side effects.

Not all side effects reported for VOXIDEX are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while using VOXIDEX, please consult your healthcare provider for advice.

If any of the following happens, stop using VOXIDEX 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 VOXIDEX. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- If you experience/see halos, blurred vision, or pain as these may be symptoms of increased ocular pressure (glaucoma, ocular hypertension).
- If you experience worsening fatigue and muscle weakness, loss of appetite, and weight loss as these may be symptoms of depression of your adrenal gland/Cushing's syndrome.
- If you experience eye irritation, a sensation of a foreign body in your eye, watering of the eye, pain in the eye or photosensitivity as these may be signs of corneal disorders.
- If you experience setting of calcium on the surface of the eye (calcification of the cornea).
- If you experience tears and a sandy sensation in your eye (crystalline keratopathy).
- If you experience small holes on the surface of the eye (perforation of the cornea).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Very common side effects:

- Burning of the eye, decreased vision.

Uncommon side effects:

- Headache, alteration in taste;
- eye irritation, abnormal sensation in eye, lid matting, eye discomfort, dryness of the eye, redness of the eye, photosensitivity, eye infection;
- runny nose;
- nausea, tongue disorder;
- itchy skin.

Very rare side effects:

- Drooping eye lid;
- dilation of the pupil.

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, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

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

5. How to store VOXIDEX

Store all medicines out of reach of children.

Store at or below 30 °C, in original packaging.

Discard within 28 days after first opening.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

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 VOXIDEX contains

The active substances in VOXIDEX are levofloxacin hemihydrate equivalent to 5 mg of levofloxacin per 1 ml and dexamethasone sodium phosphate equivalent to 1 mg of dexamethasone per 1 ml.

The other ingredients are sodium phosphate monobasic monohydrate, sodium phosphate dibasic dodecahydrate, sodium citrate, sodium hydroxide / hydrochloric acid (for pH adjustment), water for injection.

Preservative: Benzalkonium chloride 0,005 % *m/v*

What VOXIDEX looks like and contents of the pack

VOXIDEX is supplied as an eye drops solution in a bottle and looks like a clear, greenish-yellow solution, free from visible particles.

VOXIDEX is packaged in a white low-density polyethylene (LDPE) bottle, with a white low-density polyethylene (LDPE) dropper and sealed with a white high-density polyethylene (HDPE) screw cap.

A sealed and labelled bottle, filled with 5 ml of the eye drops solution, is packed into an outer carton.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

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Hotline: 0800 122 912

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Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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