Patient Information Leaflet

SCHEDULING STATUS

S4

OCTUDEX (Eye drop, suspension)

(Tobramycin and Dexamethasone)

Read all of this leaflet carefully before you start using OCTUDEX

- 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.

OCTUDEX 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 **OCTUDEX** is and what it is used for
2. What you need to know before you use **OCTUDEX**
3. How to use **OCTUDEX**
4. Possible side effects
5. How to store **OCTUDEX**
6. What **OCTUDEX** is and what it is used for

1. What OCTUDEX is and what it is used for

OCTUDEX contains two active substances, dexamethasone hydrochloride and tobramycin.

OCTUDEX is used to reduce inflammation and to prevent infection of the eye following surgery to the eye.

2. What you need to know before you use OCTUDEX

Do not use OCTUDEX:

- If you are hypersensitive (allergic) to dexamethasone hydrochloride or tobramycin or any of the other ingredients of **OCTUDEX** (listed in section 6).
- If you suffer from any viral (herpes infection) or fungal infection or think that you have any type of infection of the eye. Use of corticosteroids may make infections worse.
- If you require treatment for injury to the cornea or surface of the eye.
- If you have an uncomplicated foreign body removed from your eye.
- If you have a sticky discharge from your eye.
- If you have a red eye that has not been seen by a doctor
- **OCTUDEX** is not recommended for use whilst soft contact lenses are being worn.

Warnings and precautions

Take special care with OCTUDEX:

- If you suffer from diabetes mellitus (sugar diabetes) you may be more likely to develop blurred vision (cataracts) or increased pressure inside the eye (glaucoma).
- If you have a family history of increased eye pressure the risk of developing it may be increased.
- Secondary eye infection may develop after prolonged use or if you are using **OCTUDEX** for 10 days or longer it is important that you have regular eye examinations by your eye doctor. This is especially important in children as the risk is greater.
- If you use **OCTUDEX** for a long period of time, you may become more susceptible to eye infections, have increased pressure in your eye(s) or develop cataracts.
- If you experience blurred vision or other visual disturbances or ulcers or infection of the eye or your symptoms get worse or suddenly return, please consult your doctor. You may become more susceptible to eye infections with the use of **OCTUDEX**.
- If you experience allergic reactions with **OCTUDEX**, discontinue use and consult your doctor. Allergic reactions may vary from localised itching or skin redness to severe allergic reactions

(anaphylactic reaction) or serious skin reactions. These allergic reactions may occur with other topical or systemic antibiotics of the same family (aminoglycoside type).

- If you have a disorder causing a thinning of the eye tissues, following a corneal transplant. Corticosteroids may cause further thinning and possible perforation, and may delay the healing of your eye wound. Topical non-steroidal anti-inflammatory drugs (NSAIDs) are also known to slow or delay healing. If you use topical NSAIDS and corticosteroids together, it may increase the potential for healing problems.
- If you have or if you have ever had conditions such as in which the muscles become weak and tire easily (myasthenia gravis) or trembling, rigid posture, slow movements and a shuffling, unbalanced walk (Parkinson's disease), ask your doctor for advice. Antibiotics of this kind may worsen muscle weakness.
- 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. Suppression of the adrenal gland function may develop after stopping a long-term or intensive treatment with **OCTUDEX**. Talk to your doctor before stopping the treatment by yourself. These risks are especially important in children and patients treated with a drug called ritonavir or cobicistat (medicines used to treat HIV/AIDS).
- Signs and symptoms of adrenal suppression include fatigue; light-headedness upon standing or difficulty standing, muscle weakness, fever, weight loss, anxiety, nausea, vomiting, diarrhoea, headache, sweating, changes in mood or personality, and joint and muscle pains.

Important information if you wear contact lenses

Contact lens wear is not recommended during treatment of an ocular infection or inflammation.

Children and adolescents

- Intraocular pressure (increased pressure of the eye) should be checked frequently, this is especially important in children below 6 years of age receiving dexamethasone-containing products.

Other medicines and OCTUDEX

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

- Especially tell your doctor if you are using topical NSAIDs. If you use topical steroids and topical NSAIDs together, it may increase corneal healing problems. Tell your doctor if you are using ritonavir or cobicistat (medicines used to treat HIV/AIDS), as this may increase the amount of dexamethasone in the blood.

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 taking this **OCTUDEX**.

You should not use **OCTUDEX** when you are pregnant.

Driving and using machines

If you experience temporary blurred vision or other visual disturbances after using **OCTUDEX** you should not drive or operate machinery until your vision is clear.

Temporarily blurred vision or other visual disturbances with use of **OCTUDEX** may affect mental and/or physical abilities to perform or execute tasks or activities requiring mental alertness, judgment and/or sound coordination and vision.

It is not always possible to predict to what extent **OCTUDEX** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **OCTUDEX** affects them.

OCTUDEX contains benzalkonium chloride.

OCTUDEX contains benzalkonium chloride (as preservative) 0,01 % *w/v*

Avoid contact with soft contact lenses.

Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. In case you are allowed to wear 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

3. How to use OCTUDEX

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

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

SHAKE WELL BEFORE USE. STORE BOTTLE UPRIGHT.

If you are using other eye drops or eye ointments, wait at least 5 minutes between using each one. Eye ointments should be administered last.

When you first open the bottle and remove the cap, remove the snap ring and throw it away. This will prevent the ring falling into the eye and causing injuries.

The usual dose is one drop into the eye to be operated on every 4 hours whilst awake, for three days before surgery.

After surgery put in two drops every two hours for two days beginning with the first dressing change. From the third day put in one drop four times a day for one week. Thereafter put in one drop once daily for ten days. No further treatment should be used without further evaluation by your doctor.

Your doctor will however tell you how to use **OCTUDEX.**

Your doctor will tell you how long your treatment with **OCTUDEX** will last.

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

Directions for use

OCTUDEX Eye Drops

1. First wash your hands.

2. Sit down in front of a mirror so that you can see what you are doing.

3. Shake the bottle well. Remove the cap from the bottle.

4. Hold the bottle upside down in one hand between your thumb and middle finger.

5. Tilt your head back and with the index finger of the same hand pull the lower eyelid away from the eye to form a pouch.

6. Place the dropper tip close to, but not touching, your eye and gently tap the base of the bottle with your forefinger so that one drop falls into the gap between the eye and the lower lid.

7. Gently close your eye. Do not blink. Keep the eye closed for 1 or 2 minutes while pressing lightly with your finger on to the inner corner of the eye to allow the medicine to be absorbed.

8. Immediately after using the eye drops, wash your hands to remove any medicine that may be on them.

9. To keep the medicine as germ-free as possible, do not touch the applicator tip to any surface (including the eye). Also, keep the container tightly closed.

If you use more OCTUDEX than you should

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

If you put too much **OCTUDEX** into your eye(s) it can be washed out of your eye(s) with warm tap water.

If you forget to use OCTUDEX

If you forget a dose, just use it as soon as possible. However, if it is almost time for your next regular dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

If you stop using OCTUDEX

Use **OCTUDEX** for the period of time advised by your doctor or pharmacist.

If you have any further questions on the use of **OCTUDEX**, ask your doctor or pharmacist.

4. Possible side effects

OCTUDEX can have side effects.

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

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

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- shortness of breath/wheezing;
- fainting.
- severe skin reactions such as blistering which may be accompanied by sore throat,
- fever or headache

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **OCTUDEX**. 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:

• Erythema multiforme (a skin reaction as a rash on the body where each mark resembles a red hive)**;**

• tightness of the throat.

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

Tell your doctor if you notice any of the following:

The following side effects have been reported less frequently:

• increased pressure in your eye (s);

• eye irritation, eye pain, eye itching;

• watery eyes, eye discomfort;

• redness;

• blurred vision;

• dry eye;

• eye allergy;

• eye surface inflammation;

• increase in pupil size;

• eyelid redness, eyelid swelling;

• increased tear production;

• dizziness;

• nausea;

• abdominal discomfort;

• headache;

The following side effects have been reported but the frequency is unknown:

• 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') (*see section 2 Warnings and precautions)*.

• If **OCTUDEX** is used for more than 24 days, it may cause you to get an infection and the healing of your wound may also be delayed.

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

How to store OCTUDEX

Store all medicines out of reach of children.

Store at or below 25 °C.

Do not refrigerate.

Protect from light.

The expiry date is printed on each bottle and on the outer packaging. Do not use the product after the expiry date.

You must discard the product one month after opening. You should ask your pharmacist to dispose of any unused medicine for you.

4. Contents of the pack and other information

OCTUDEX (Eye drops, suspension)

Each ml eye drop contains:

Tobramycin 3,0 mg

Dexamethasone 1,0 mg

Benzalkonium chloride (as preservative)

0,01 % *w/v*

The other ingredients are:

Benzalkonium chloride, disodium edetate, hydroxy ethyl cellulose, sodium chloride, sodium sulphate anhydrous tyloxapol and water.

What OCTUDEX looks like and Contents of the pack.

White to off suspension is packed in a 5 ml natural LDPE dropper bottle with a 13 mm LDPE sterile plug and sealed with a 13 mm opaque HDPE Pilfer-proof sterile cap.

Holder of Certificate of Registration

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