Clean Proposed Patient Information Leaflet for Medicines for Human Use:

[PRODUCT NAME]

SCHEDULING STATUS: S4

[PRODUCT NAME] EYE DROPS, SUSPENSION

Dexamethasone and Tobramycin

Contains Preservative: 0,01 % *(m/v)* benzalkonium chloride per mL.

Read all of this leaflet carefully before you start using [PRODUCT NAME]

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your health care provider.
- [PRODUCT NAME] 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 [PRODUCT NAME] is and what it is used for
2. What you need to know before you use [PRODUCT NAME]
3. How to use [PRODUCT NAME]
4. Possible side effects
5. How to store [PRODUCT NAME]
6. Contents of the pack and other information

1. What [PRODUCT NAME] is and what it is used for

[PRODUCT NAME] is a sterile eye drop, suspension.

[PRODUCT NAME] contains the active substances dexamethasone which is a corticosteroid and tobramycin which is an antibiotic active against a wide range of bacteria that may infect the eye.
It 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 [PRODUCT NAME]

Do not use [PRODUCT NAME]

- if you are hypersensitive (allergic) to dexamethasone and/or tobramycin or any of the other ingredients of [PRODUCT NAME] (listed in section 6)
- if you suffer from a herpes infection of the eye
- if you suffer from any viral or fungal infection of the eye
- if you require treatment for injury to the cornea or surface of the eye
- [PRODUCT NAME] is not recommended for use whilst soft contact lenses are being worn.

If you are not sure whether you should use [PRODUCT NAME], contact your health care provider.

Warnings and precautions

Take special care with [PRODUCT NAME]

- 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

- if you experience allergic reactions with [PRODUCT NAME], discontinue use and consult your health care provider. Allergic reactions may vary from localized 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 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
- if you have or if you have ever had conditions such as myasthenia gravis or Parkinson's disease, ask your health care provider for advice as antibiotics of this kind may worsen muscle weakness
- if you experience blurred vision or other visual disturbances, contact your health care provider
- if you have a disorder causing a thinning of the eye tissues, such as rheumatoid arthritis, Fuch's dystrophy or following a corneal (the clear layer at the front of the eye) 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 ulcers or infection of the eye, [PRODUCT NAME] may aggravate the condition or worsen the infection
- secondary eye infection may develop after prolonged use
- if you are using [PRODUCT NAME] for a long period of time, you may become more susceptible to eye infections, have increased pressure in your eye(s) or develop cataracts. It is important that you

have regular eye examinations by your ophthalmologist. This is especially important in children as the risk is greater.

Other medicines and [PRODUCT NAME]

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

Tell your health care provider about all medicines, including other eye drops, that you are using or plan to use, including those obtained without a prescription.

Especially tell your health care provider if you are using topical NSAIDs. If you use topical steroids and topical NSAIDs together, it may increase corneal healing problems. Tell your health care provider if you are using ritonavir or cobicistat, as this may increase the amount of dexamethasone in the blood.

Pregnancy and breastfeeding

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

[PRODUCT NAME] is not recommended during pregnancy because the safety of taking [PRODUCT NAME] during pregnancy is not known.

If you are breastfeeding, caution should be observed when taking [PRODUCT NAME] because it is not known if the medicine is passed into breast milk.

Driving and using machines

Temporarily blurred vision or other visual disturbances with use of [PRODUCT NAME] may affect the ability to drive or use machines. If blurred vision occurs with application, wait until your vision clears before driving or using machinery.

[PRODUCT NAME] 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 health care provider.

3. How to use [PRODUCT NAME]

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

Always use [PRODUCT NAME] exactly as your health care provider has told you. Check with your health care provider if you are not sure.

SHAKE WELL BEFORE USE. STORE BOTTLE UPRIGHT.

When you first open the bottle and remove the cap, remove the tamper evident 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.

Duration of administration

Your health care provider will tell you how long your treatment with [PRODUCT NAME] will last. Do not change the dose of the medicine without consulting your health care provider. If you must stop treatment, contact your health care provider immediately.

If you have the impression that the effect of [PRODUCT NAME] is too strong or too weak, talk to your health care provider.

Method of administration

Insert the recommended dose into the affected eye(s).

[PRODUCT NAME] is for is for ocular use only.

Multi-dose eye drops:

Do not allow the tip of the container to touch the eye or areas around the eye. It may become contaminated with bacteria that can cause eye infections leading to serious damage of the eye, even loss of vision. To avoid possible contamination of the container, wash your hands before using this medicine and keep the tip of the container away from contact with any surface. If you think your medicine may be contaminated, or if

you develop an eye infection, contact your health care provider immediately concerning continued use of this bottle.

Instructions for use

1. First wash your hands.
2. **Shake the bottle well.**
3. To open the bottle, unscrew the cap by turning it to the left. Do not pull the cap directly up and away from the bottle. Pulling the cap directly up will prevent your dispenser from operating properly.
4. Tilt your head back and use your finger to gently pull down your lower eyelid to form a pouch between your eye and eyelid.



5. Invert the bottle and press lightly with the thumb or index finger until a single drop is dispensed into the eye as directed by your health care provider. **DO NOT LET YOUR EYE OR EYELID TOUCH THE DROPPER TIP.**



6. After using [PRODUCT NAME] press a finger into the corner of your eye, by the nose, or close your eyelids for 2 minutes. This helps to stop the medicine from getting into the rest of the body.
7. Repeat steps 4 and 5 in the other eye if instructed to do so by your health care provider.

8. Replace the cap by turning until it is firmly touching the bottle. Do not overtighten or you may damage the bottle and cap.

If you wear soft contact lenses

Do not use the drops with your soft contact lenses in. After using the drops wait 15 minutes before putting your lenses back in.

If you are using other eye drops

If you are using [PRODUCT NAME] with another eye drop, the drops should be instilled at least 5 minutes apart.

If you use more [PRODUCT NAME] than you should

In the event of overdosage, consult your health care provider. If not available, contact the nearest hospital or poison centre.

If you put too much [PRODUCT NAME] into your eye(s) it can be washed out of your eye(s) with warm tap water.

If you forget to use [PRODUCT NAME]

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

It is important to use [PRODUCT NAME] as prescribed by your health care provider.

If you miss a dose, apply the missed dose as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to your regular dosing schedule.

Do not double the dose to make up for the forgotten individual dose.

4. Possible side effects

[PRODUCT NAME] can have side effects.

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

The following side effects have been reported in studies with [PRODUCT NAME]:

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

• itchy rash or hives

• swelling of the face, lips, tongue or other parts of the body

• shortness of breath/wheezing

• severe skin reactions such as blistering which may be accompanied by sore throat, fever or headache.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- eye pain, eye itching, eye discomfort, increase pressure in the eye, eye irritation, eye infection, eye allergy, blurred vision, dry eye, eye redness
- runny nose, tightness of the throat
- bad taste.

Side effects with frequency unknown:

- allergic reaction, hypersensitivity, dizziness, headache, eyelid swelling, eyelid redness, increase in pupil size, increase tears production, nausea, stomach discomfort, rash, face swelling, itching.

Side effects that have been reported with use of individual ingredients of [PRODUCT NAME]

Side effects with dexamethasone:

Frequent side effects:

- headache
- eye redness, eyelid redness, abnormal feeling in the eye
- secretions from the nose that drain into the throat causing congestion and cough.

Less frequent side effects:

- eye infection
- decrease hormone (such as cortisol) secretion
- reduced sharpness of vision, increased eye pressure, visual field defects
- slow healing
- damage to the cornea (white part of the eye).

Side effects with tobramycin:

Frequent side effects:

- eye redness, eye pain.

Less frequent side effects:

- eye infection, eye itching, eye irritation (burning and stinging upon instillation), blurred vision, eye redness, eyelid swelling, eyelid itching, increase tears production, eye pain, inflammation of the clear tissue on the front of the eye (cornea)
- reddening of the skin around the eye.

If you notice any side effects not mentioned in this leaflet, please inform your health care provider.

Reporting of side effects

If you get side effects, talk to your health care provider. 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 [PRODUCT NAME]**.**

Suspected side effects can also be reported directly to the Holder of the Certificate of Registration via medsafety@austell.co.za

5. How to store [PRODUCT NAME]

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Keep in the original container to protect from light.
- Do not use more than 28 days after opening. Once opened, the suspension may become contaminated, which can cause eye

infections. Therefore, you must throw away the bottle 4 weeks (28 days) after you first opened it.

- Do not use this medicine after the expiry date which is printed on the carton and bottle after EXP. The expiry date refers to the last day of that month.
- 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 [PRODUCT NAME] contains

- The active substance is dexamethasone and tobramycin.
- The other ingredients are benzalkonium chloride, edetate disodium, hydroxyethyl cellulose, sodium chloride, sodium sulfate anhydrous, sodium hydroxide and/or sulfuric acid, tyloxapol and water for injection.

What [PRODUCT NAME] looks like and contents of the pack

[PRODUCT NAME] eye drops suspension, is a white, homogenous suspension.

[PRODUCT NAME] is available in a white LDPE bottle with a dropper, sealed with a white cap and white tamper evident ring.

Each dropper container has a capacity of 10 mL and contains 5 mL of [PRODUCT NAME].

Pack size: 1 x 5 mL dropper container

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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