## 1.3.2 Proposed Clean Patient Information Leaflet

**SCHEDULING STATUS:**

S4

**PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM**

**ALREX Ophthalmic Suspension**

Loteprednol etabonate 0,2 % *w/v*

**Read all of this leaflet carefully before you start using ALREX**

Keep this leaflet. You may need to read it again.

- If you have further questions, please ask your doctor or your pharmacist.
- **ALREX** has been prescribed for you personally and you should not share your medicine with other people. It may harm then, even if their symptoms are the same as yours.

**WHAT ALREX CONTAINS**

The active substance is loteprednol etabonate. There is 2,00 mg (0,2 % *w/v*) of loteprednol etabonate per 1 mℓ of the medicine.

The preservative is benzalkonium chloride. There is 0,10 mg (0,01 % *w/v*) of benzalkonium chloride per 1 mℓ of the medicine.

The other ingredients are edetate disodium dihydrate, glycerin, povidone (K-90F), tyloxapol.

**WHAT ALREX IS USED FOR:**

**ALREX** is an eye preparation that contains a corticosteroid.

It is used as short-term treatment of the symptoms of seasonal allergic inflammation of the eye in adults.

**BEFORE YOU USE ALREX:**

**Do not use ALREX:**

- if you have infection of the eye. It may mask infection or worsen the existing infection
- if you are allergic to loteprednol, other corticosteroids (e.g. cortisone) or any of the other the ingredients of **ALREX**
- if you are pregnant or breastfeeding
- if you have glaucoma (increased pressure inside the eye)
- in children under the age of 18 years

**Take special care with ALREX:**

- If signs and symptoms fail to improve after two days, consult your doctor.
- If **ALREX** is used for 10 days or longer, pressure inside your eye should be monitored by your doctor.
- This bottle of **ALREX** is sterile when packaged. Do not allow the dropper tip to touch any surface, as this may introduce germs into your medicine.
- **ALREX** should be discarded 28 days after opening.
- Safety and effectiveness in small children have not been proven.

**Pregnancy and Breastfeeding:**

**ALREX** should not be used during pregnancy or if you are breastfeeding your baby.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

**Driving and using machinery:**

You may experience abnormal or blurred vision for a while after instilling **ALREX** into your eyes. Wait until your vision is clear before driving or operating machinery.

**Important information about some of the ingredients of ALREX:**

- **ALREX** contains benzalkonium chloride, do not wear soft contact lenses when using it.
- Benzalkonium chloride can cause damage to your eyes if you use it for too long or too often. Your doctor should examine your eyes regularly.

**Using other medicines with ALREX:**

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

- Do not use **ALREX** if you are using other medicines that have a tendency to increase the pressure inside the eye.
- Some medicines may increase the effects of **ALREX** and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **ALREX** with these

medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

**HOW TO USE ALREX:**

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

Always use **ALREX** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is one or two drops into the conjunctival sac of the affected eye(s) four times daily. During initial treatment within the first week, the dosing may be increased up to one drop every hour, if necessary.

Do not use **ALREX** for longer than six weeks.

If you are using other eye medicines together with **ALREX,** you should wait at least 10 minutes in between instilling the products.

Do not swallow.

Shake well before use.

**POSSIBLE SIDE EFFECTS**

**ALREX** can have side effects.

If the following happens, stop using **ALREX** immediately and tell your doctor:

- Increased pressure within the eye
- Allergic reaction
- Skin rash or hives
- Swelling of the face

- Chest pain
- Changes in the way your heart beats

These can be serious side effects and you may need medical attention.

The following are frequent side effects. If any of these become bothersome, stop using **ALREX** and tell your doctor:

- Abnormal or blurred vision
- Redness in the eye
- Burning or stinging when putting drops in the eye or at any time during treatment
- Swelling of the eyes
- Discharge from the eyes
- Dry eyes or excessive tearing
- Sensation of having an object in your eye
- Eye discomfort or itchy eyes
- Sensitivity to light
- Headache

The following side effects occur less frequent. You should tell your doctor if any of the following become bothersome:

- Swelling and redness of the eyelid
- Painful eyes
- Sticky eyes
- Eye irritation
- Feeling tired or weak
- Fever and chills

- General pain
- Nervousness
- Taste disturbances
- Diarrhoea, nausea or vomiting
- Migraine
- Runny nose, sore throat or cough
- Urine infection

The following side effects have also been reported in patients using **ALREX.** Tell your doctor if you are concerned about any of the following:

- Skin rash or skin discolouration
- Sweating
- Muscle spasms
- Dizziness
- Tingling feeling (pins and needles)
- Trembling, shaking or twitching
- Anxiety
- Inability to sleep
- Depression
- Discharge from the ear or ear pain
- Heartburn
- Increased blood pressure
- Change of voice
- Asthma
- Abnormalities of your hair

- Loss of appetite

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

## STORING AND DISPOSING OF ALREX

Store upright.

Store at or below 25 °C.

Do not refrigerate or freeze.

Do not use for more than 28 days after first opening.

Keep bottle tightly closed when not in use. Store in an upright position.

Do not use after the expiry date stated on the bottle and the carton.

Keep all medicines out of the reach and sight of children.

## PRESENTATION OF ALREX

A white plastic dropper bottle with a control drop tip containing 1 mℓ, 2,5 mℓ, 5 mℓ or 10 mℓ of suspension. The labelled plastic bottle is packed together with a package insert into a printed unit carton.

## IDENTIFICATION OF ALREX

A white to off-white milky suspension.

## REGISTRATION NUMBER

38/15.2/0203

176 **NAME AND BUSINESS ADDRESS OF THE REGISTRATION**

177 **HOLDER**

178 Soflens (Pty) Ltd

179 254 Hall Street

180 Centurion

181 0157

182 **DATE OF PUBLICATION**

183 Date of registration: 07 July 2006

184 Date of revision: 19 February 2016