

1.3.2 Proposed Clean Patient Information Leaflet

1 **SCHEDULING STATUS:**

2 S4

3 **PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL**
4 **FORM**

5 **ALREX Ophthalmic Suspension**

6 Loteprednol etabonate 0,2 % w/v
7

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

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

- 10 • If you have further questions, please ask your doctor or
11 your pharmacist.
12 • **ALREX** has been prescribed for you personally and you
13 should not share your medicine with other people. It may
14 harm them, even if their symptoms are the same as yours.
15

16 **WHAT ALREX CONTAINS**

17 The active substance is loteprednol etabonate. There is 2,00 mg (0,2
18 % w/v) of loteprednol etabonate per 1 ml of the medicine.

19 The preservative is benzalkonium chloride. There is 0,10 mg (0,01 %
20 w/v) of benzalkonium chloride per 1 ml of the medicine.
21

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

24 **WHAT ALREX IS USED FOR:**

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

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

28 **BEFORE YOU USE ALREX:**

29 **Do not use ALREX:**

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

37 **Take special care with ALREX:**

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

47 **Pregnancy and Breastfeeding:**

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

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

52 **Driving and using machinery:**

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

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

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

62
63 **Using other medicines with ALREX:**

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

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

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

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

77

78 **HOW TO USE ALREX:**

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

80

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

83

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

87

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

88

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

90

91 Do not swallow.

92

92 Shake well before use.

93

93 **POSSIBLE SIDE EFFECTS**

94

94 **ALREX** can have side effects.

95

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

97

98 • Increased pressure within the eye

99

99 • Allergic reaction

100

100 • Skin rash or hives

101

101 • Swelling of the face

102 • Chest pain

103 • Changes in the way your heart beats

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

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

108 • Abnormal or blurred vision

109

• Redness in the eye

110

111 • Burning or stinging when putting drops in the eye or at any time
112 during treatment

113

• Swelling of the eyes

114

• Discharge from the eyes

115

• Dry eyes or excessive tearing

116

• Sensation of having an object in your eye

117

• Eye discomfort or itchy eyes

118

• Sensitivity to light

119

• Headache

120

120 The following side effects occur less frequent. You should tell your

121 doctor if any of the following become bothersome:

122

• Swelling and redness of the eyelid

123

• Painful eyes

124

• Sticky eyes

125

• Eye irritation

126

• Feeling tired or weak

127

• Fever and chills

- 128 • General pain
- 129 • Nervousness
- 130 • Taste disturbances
- 131 • Diarrhoea, nausea or vomiting
- 132 • Migraine
- 133 • Runny nose, sore throat or cough
- 134 • Urine infection

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

- 138 • Skin rash or skin discolouration
- 139 • Sweating
- 140 • Muscle spasms
- 141 • Dizziness
- 142 • Tingling feeling (pins and needles)
- 143 • Trembling, shaking or twitching
- 144 • Anxiety
- 145 • Inability to sleep
- 146 • Depression
- 147 • Discharge from the ear or ear pain
- 148 • Heartburn
- 149 • Increased blood pressure
- 150 • Change of voice
- 151 • Asthma
- 152 • Abnormalities of your hair

- 153 • Loss of appetite

154 Not all side effects reported for this medicine are included in this
155 leaflet. Should your general health worsen or if you experience any
156 untoward effects while taking this medicine, please consult your
157 doctor, pharmacist or other health care professional for advice.
157 If you notice any side effects not mentioned in this leaflet, please
159 inform your doctor or pharmacist.

160 **STORING AND DISPOSING OF ALREX**

161 Store upright.

162 Store at or below 25 °C.

163 Do not refrigerate or freeze.

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

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

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

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

168 **PRESENTATION OF ALREX**

169 A white plastic dropper bottle with a control drop tip containing 1 ml,
170 2,5 ml, 5 ml or 10 ml of suspension. The labelled plastic bottle is
171 packed together with a package insert into a printed unit carton.

172 **IDENTIFICATION OF ALREX**

173 A white to off-white milky suspension.

174 **REGISTRATION NUMBER**

175 38/15.2/0203

Soflens Pharmaceuticals (Pty) Ltd

1.3.2

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Date of approval: 2016/02/19

Loteprednol etabonate 2,00 mg/ml, Ophthalmic suspension SR PIN submission : 2017/01/05

Date of submission: 2017/09/27

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