

APPROVED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S1

PRODUCT NAME

Iliadin® Aloe

Oxymetazoline hydrochloride 0,5 mg

Each 1 ml solution contains:

0,5 mg/0,05 % m/v Oxymetazoline hydrochloride

Benzalkonium chloride 0,02 % m/v and Benzyl l alcohol 0,2 % m/v as preservative

Contains sweetener: Acesulfame potassium 0,15 mg & Sorbitol 71,4 mg per 1 ml

Contains sodium: 2,066 mg per 1 ml

Read all of this leaflet carefully because it contains important information for you

iliadin Aloe is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use **iliadin Aloe** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **iliadin Aloe** with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after **5** days.

What is in this leaflet

1. What **iliadin Aloe** is and what it is used for
2. What you need to know before you use **iliadin Aloe**
3. How to use **iliadin Aloe**
4. Possible side effects
5. How to store **iliadin Aloe**
6. Contents of the pack and other information

1. What iliadin Aloe is and what it is used for

iliadin Aloe is indicated for the relief of nasal congestion due to the common cold (acute rhinitis), sinusitis (inflammation or swelling of the tissue lining the sinuses), allergic rhinitis (an allergic reaction of the lining inside the nasal).

iliadin Aloe is also used to assist in the treatment of middle ear infection (inflammation of the area behind the eardrum).

2. What you need to know before you take iliadin Aloe

Do not take iliadin Aloe:

- if you are hypersensitive (allergic) to oxymetazoline hydrochloride, benzalkonium chloride or any of the other ingredients of **iliadin Aloe** (listed in section 6).
- if you have rhinitis sicca (abnormally dry nose, and/or inflamed skin or mucous membranes of your nostrils or scabs in your nose).
- if you have had an operation to remove your pituitary gland.

Do not give **iliadin Aloe** to children below six years of age.

Warnings and precautions

51 **Take special care with iliadin Aloe**

- 52 • If you are taking (or have taken during the last two weeks) monoamine oxidase inhibitors (MAO
53 inhibitors) or tricyclic antidepressants (used in the treatment of depression), antiparkinson's
54 medicines such as bromocriptine (used in the treatment of Parkinsons's disease).
- 55 • Medicines that potentially increase blood pressure.
- 56 • If you suffer from increased eyeball-pressure (narrow-angle glaucoma).
- 57 • If you suffer from severe heart diseases (e.g. coronary heart disease, angina, high blood pressure,
58 cardiac asthma).
- 59 • If you suffer from phaeochromocytoma (tumor of adrenal gland tissue i.e. chromaffin cells)
- 60 • If you suffer from metabolic disorders (e.g. overactive thyroid, diabetes mellitus, porphyria).
- 61 • If you have enlargement of the prostate.

62 Long-term use and overdosage of **iliadin Aloe** should be avoided.

63 **Do not exceed the recommended dose.**

64 iliadin Aloe should be used for a maximum of 5 consecutive days to avoid a rebound-effect and drug-
65 induced rhinitis (recurrent inflammation/congestion of the nasal mucous membrane).

66

67 The effect of **iliadin Aloe** may be reduced with long-term use or overdose. This may lead to use of higher
68 doses or to more frequent usage which, in turn, can result in permanent use. If long term use or overdose
69 occurs, treatment should be discontinued immediately.

70

71 Continuous use may cause the tissue that lines the nose and the bone underneath to shrink down, causing
72 blocked nose, swelling and irritation inside the nose.

73 Rebound effects and reduced effect should stop once use of **iliadin Aloe** is discontinued.

74

75 Medical supervision is indicated in patients with chronic rhinitis.

76 Dosages higher than recommended may only be used under medical supervision.

77

78 **Other medicines and iliadin Aloe**

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

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

- 82 • Monoamine oxidase inhibitors (MAOIs) or tricyclic antidepressants used for the treatment of
83 depression).

84 **iliadin Aloe** may cause high blood pressure if used during treatment with a MAOI or, tricyclic
85 antidepressants (e.g. amitriptyline and imipramine).

- 86 • Medicines used for the treatment of high blood pressure.

- 87 • Medicines used to treat Parkinson's disease e.g. bromocriptine.

88

89 **Pregnancy, breastfeeding and fertility**

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

92 Due to insufficient information available on the use of the product during pregnancy and breast-feeding,
93 **iliadin Aloe** should only be used on the advice of a doctor.

94

95 **Driving and using machines**

96 **iliadin Aloe** does not impair driving or the use of machinery.

97 However some possible side effects may occur with prolonged use of **iliadin Aloe** which may have an
98 effect on driving and using machinery.

99 **3. How to take iliadin Aloe**

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

101 **Always take iliadin Aloe** exactly as your healthcare provider has told you. Check with your health care

102 provider if you are unsure.

103 **iliadin Aloe** is intended for children over the age of six years and for adults.

104 The usual dose is:

105 Adults: One -Two (1-2) sprays into each nostril 2 - 3 times a day. See diagram for directions for use.

106 Children over 6 years: 1 spray into each nostril two – three (2 – 3) times a day.

107 Children under 6 years: Do not use.

108 The single dose given for **iliadin Aloe** must not be administered more than 3 times a day.

109 Do not administer for longer than 5 days. Do not exceed the recommended dosage. If symptoms persist,
110 consult a health care provider.

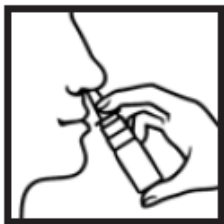
111 If you have the impression that the effect of **iliadin Aloe** is too strong or too weak, tell your doctor or
112 pharmacist.

113

114 **Method of administration**

115 **iliadin Aloe**

116 For best results keep both the head and spray bottle in an upright position. Remove cap by pulling and
117 insert the nozzle of the spray loosely into the nostril with the middle and forefinger around the bottom of the
118 nozzle and the thumb on the base of the bottle. Depress the spray mechanism (as shown in the diagram)
119 thus producing a fine mist. Sniff in to ensure an even distribution of the spray. Withdraw from nostril and
120 release the spray mechanism. Repeat for the other nostril.



121

122

123 **If you take more iliadin Aloe than you should**

124 Overdosage may occur after nasal or accidental oral administration

125 Symptoms of an overdose may be:

126 Hypertension, tachycardia, palpitations, cardiac dysrhythmia, cardiac arrest, cardiac failure, sweating,

127 agitation, convulsion, mydriasis, nausea, vomiting, cyanosis, fever, spasms, circulatory collapse, pulmonary

128 oedema, respiratory disorders, psychic disorders, drowsiness, paleness, miosis, decrease in body

129 temperature, bradycardia, shock-like hypotension, apnoea, convulsions and coma.

130 In children above 6 years, in particular, overdose often causes dominating central nervous effects with

131 convulsions and coma, bradycardia, apnoea as well as hypertension possibly followed by hypotension.

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

133 hospital or poison control centre.

134

135 **If you forget to take iliadin Aloe**

136 Do not take a double dose to make up for forgotten individual doses

137

138 **4. Possible side effects**

139 **iliadin Aloe** can have side effects.

140 Not all side effects reported for **iliadin Aloe** are included in this leaflet. Should your general health worsen

141 or if you experience any untoward effects while taking **iliadin Aloe**, please consult your doctor, pharmacist

142 or other health care provider for advice.

143

144 **If any of the following happens, stop taking iliadin Aloe and tell your doctor immediately or go to the**
145 **casualty department at your nearest hospital:**

- 146 • Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in
147 swallowing or breathing, rash or itching.

148 • Fits or seizures.

149 • Fainting

150 These are all very serious side effects. If you have them, you may have had a serious reaction to **iliadin**
151 **Aloe**. You may need urgent medical attention or hospitalisation.

152

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

155 • Fast, irregular or pounding heartbeat

156 • High blood pressure

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

158

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

161 *The following side effects have been frequently reported:*

162 • Aqueous nasal secretions (runny nose), crusted nose.

163 *The following side effects have been reported less frequently:*

164 • Rebound congestion (increase in runny or stuffy nose).

165 • Headache or light-headedness, nervousness, trembling.

166 • Nausea

167

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

169 • Nasal discomfort (burning of the nasal mucosa), nasal dryness and sneezing, swelling of the lining
170 of the nasal mucosa, bleeding from the nostril, throat discomfort.

171 • Drowsiness, sleep or calm induced by medication, hallucinations, tremor, anxiety, restlessness,
172 irritability, nervousness, Convulsions, trouble sleeping

- Hypersensitivity (swelling, rash)
- Palpitations, tachycardia, increased blood pressure
- Fatigue or tiredness,

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 other 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 **iliadin Aloe**.

5. How to store iliadin Aloe

- Store at or below 25 °C.
- Protect from light. Keep well closed.
- Keep in original packaging until required for use.
- 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).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Use within 12 months of first opening the bottle.

6. Contents of the pack and other information

What iliadin Aloe contains

Each 1 ml of the solution contains:

0,5 mg/0,05 % m/v Oxymetazoline hydrochloride

Applicant: P&G South African Trading (Pty) Ltd
Product name: iliadin® Aloe
Dosage form and strength: Each 1,0 ml solution contains 0,5 mg oxymetazoline hydrochloride

MODULE 1
1.3.2

199 Benzalkonium chloride 0,02 % *m/v* and benzyl alcohol 0,2 % *m/v* as preservative

200 Contains sweetener: Acesulfame potassium 0,15 mg and Sorbitol 70 % 71,4 mg

201

202 **The other ingredients are:**

203 Sorbitol

204 Sodium citrate dihydrate (for pH-adjustment)

205 Polysorbate 80

206 Citric acid, anhydrous (for pH-adjustment)

207 Levomenthol

208 Cineole (eucalyptol)

209 Disodium edetate

210 Aloe dry extract

211 Levocarvone

212 Water, purified.

213

214 **What iliadin Aloe looks like and contents of the pack**

215 15 ml Brown glass bottle with a metering pump (polypropylene).

216

217 **Holder of certificate of registration**

218 P&G South African Trading (Pty) Ltd.

219 10th Floor, Alice Lane Towers, 15 Alice Lane

220 Sandton, 2196

Applicant: P&G South African Trading (Pty) Ltd
Product name: iliadin® Aloe
Dosage form and strength: Each 1,0 ml solution contains 0,5 mg oxymetazoline hydrochloride

MODULE 1
1.3.2

221 South Africa

222

223 **This leaflet was last revised in**

224 50/16.1/0335

225

226 **Registration numbers**

227 20 September 2022

228

229 Professional information may be accessed at:

230 https://www.iliadin.com/en_ZA/home/products-information.html