

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
1.3.1.1

APPROVED PROFESSIONAL INFORMATION FOR HUMAN MEDICINES

SCHEDULING STATUS

S1

1 NAME OF THE MEDICINE

iliadin® Aloe

Strength

Each 1 ml solution contains oxymetazoline hydrochloride 0,5 mg/0,05 % m/v

Pharmaceutical form

Nasal spray, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml solution contains:

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

Benzalkonium chloride 0,02 % m/v and Benzyl 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

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Nasal spray, solution

The product is a clear liquid with a colourless to very slight yellowish colouration, free from particulate and suspended matter with a characteristic aromatic odour resembling aroma of eucalyptus and menthol.

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32 **4 CLINICAL PARTICULARS**

33 **4.1 Therapeutic indications**

34 **iliadin Aloe** is indicated for the relief of nasal congestion due to the common cold (acute rhinitis),
35 sinusitis, allergic rhinitis.

36 Indicated as adjunctive treatment in middle ear infection.

37

38 **4.2 Posology and method of administration**

39 ***Posology***

40 Adults: 1-2 sprays into each nostril 2 – 3 times a day.

41 **Paediatric population**

42 Children over 6 years: 1 spray into each nostril 2 - 3 times a day.

43 Not intended for children below the age of 6 years.

44

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

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

48

49 ***Method of Administration***

50 Metered Nose Spray for nasal use.

51

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



4.3 Contraindications

- Hypersensitivity to the active ingredient, benzalkonium chloride or any of the other ingredients listed in section 6.1.
- Rhinitis sicca (inflammation of the skin and mucosa of the nasal vestibule and encrustation).
- Children below six years of age.
- In patients following a trans-sphenoidal hypophysectomy.

4.4 Special warnings and precautions for use

In the following cases, **iliadin Aloe** may only be used after carefully weighing the risk-to-benefit ratio:

- Patients treated with monoamine oxidase inhibitors or, have taken MAOIs in the previous two weeks or, tricyclic antidepressants, and other medicines such as *stated in 4.5*.
- Medicines potentially increasing blood pressure.
- Increased intraocular pressure, especially narrow-angle glaucoma.
- Severe cardiovascular diseases (e.g. coronary heart disease, angina, hypertension, cardiac asthma).
- Pheochromocytoma.
- Metabolic disorders (e.g. hyperthyroidism, diabetes mellitus, porphyria).
- Hyperplasia of the prostate.
- **Do not exceed the recommended dose.**
- If symptoms worsen or do not improve after 3 days, physician should re-evaluate clinical situations.
- **iliadin Aloe** should be used for a maximum of 5 consecutive days to avoid a rebound-effect and

drug-induced rhinitis.

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

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

Continuous use may cause nasal congestion due to reactive hyperaemia of the nasal mucosa (rebound effect) and chronic swelling of the nasal mucosa (rhinitis medicamentosa) as well as mucosal atrophy or rhinitis sicca. Rebound effects and tachyphylaxis should stop once use of **iliadin Aloe** is discontinued.

Medical supervision is indicated in patients with chronic rhinitis.

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

4.5 Interaction with other medicines and other forms of interaction

The concomitant use of **iliadin Aloe** and certain mood-stimulating medicines with hypertensive effect (e.g. MAO inhibitors and tricyclic antidepressants) may lead to an increase in blood pressure or hypertensive crisis due to their cardiovascular activity.

The efficacy of beta-blocking drugs such as methyldopa, bethanidine, debrisoquine and guanethidine or other anti-hypertensive drugs may be reduced with concomitant use of **iliadin Aloe**.

Possible additive cardiovascular toxicity may occur when sympathomimetics are given with antiparkinsonian drugs such as bromocriptine.

4.6 Fertility, pregnancy and lactation

Pregnancy and lactation

iliadin Aloe should only be used after the consultation with a medical practitioner during pregnancy and lactation.

The recommended dosage must not be exceeded.

Fertility

No data are available on the effects of **iliadin Aloe** on human fertility.

111 **4.7 Effects on ability to drive and use machines**

112 No impairment is to be expected if used as recommended.

113 Systemic effects with involvement of the cardiovascular or central nervous system cannot be
114 excluded after prolonged administration of **iliadin Aloe** or intake of oxymetazoline containing cold
115 remedies in doses higher than recommended. In these cases, the ability to drive a vehicle or operate
116 machinery can be impaired.

117

118 **4.8 Undesirable effects**

119 **Immune system disorders:**

120 Frequency unknown: Hypersensitivity reactions (angioedema, rash, pruritus).

121 **Psychiatric disorders:**

122 Frequency unknown: Insomnia, restlessness.

123 **Nervous system disorders:**

124 Less frequent: Headache or light-headedness, nervousness, anxiety, irritability.

125 Frequency unknown: Somnolence, sedation, hallucinations, convulsions.

126 **Cardiac disorders:**

127 Frequency unknown: Palpitations, tachycardia.

128 **Vascular disorders:**

129 Frequency unknown: Hypertension (increased blood pressure).

130 **Respiratory, thoracic and mediastinal disorders:**

131 Frequent: Aqueous nasal secretions.

132 Frequent: Crusted nose.

133 Less frequent: Rebound congestion (increase in runny or stuffy nose).

134 Frequency unknown: Nasal discomfort (burning of the nasal mucosa), nasal dryness, sneezing, after
135 the effect has worn off increased swelling of the mucosa (reactive hyperaemia), epistaxis.

136 **General disorders and administration site conditions:**

137 Frequency unknown: Fatigue, tachyphylaxis (associated with long-term use or overdose).

138 Systemic effects have occurred after local administration.

139 If unexpected side effects appear, a medical practitioner should be consulted immediately.

140

141 **Reporting of suspected adverse reactions**

142 Reporting suspected adverse reactions after authorisation of the medicine is important. It allows
143 continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to
144 report any suspected adverse reactions to SAHPRA via the “**6.04 Adverse Drug Reactions**
145 **Reporting Form**”, found online under SAHPRA’s publications:

146 <https://www.sahpra.org.za/Publications/Index/8>

147

148 **4.9 Overdose**

149 Overdosage may occur after nasal or accidental oral administration.

150 The efficacy of **iliadin Aloe** may be reduced (tachyphylaxis) with long-term use or overdose. This may
151 lead to use of higher doses or to more frequent usage which, in turn, can result in permanent use. If
152 long term use or overdose occurs, treatment should be discontinued immediately.

153 The clinical picture following intoxication with imidazol-derivatives may be unclear due to the
154 occurrence of episodes of hyperactivity alternated with episodes of depression of the central nervous
155 system and of the cardiovascular and pulmonary system.

156 **Symptoms**

157 Symptoms of an overdose may be:

158 Hypertension, tachycardia, palpitations, cardiac dysrhythmia, cardiac arrest, sweating, agitation,
159 convulsion, mydriasis, nausea, vomiting, cyanosis, fever, spasms, circulatory collapse, pulmonary
160 oedema, respiratory disorders, psychic disorders, drowsiness, paleness, miosis, decrease in body
161 temperature, bradycardia, shock-like hypotension, apnoea, loss of consciousness and coma.

162

163 In children above 6 years, in particular, overdose often causes dominating central nervous effects with
164 convulsions and coma, bradycardia, apnoea as well as hypertension possibly followed by
165 hypotension.

166 **Therapeutic measures after overdosage**

167 In-house intensive-care therapy is indicated in cases of severe overdose.

168 Administration of medicinal charcoal (absorbent) or sodium sulfate (laxative) should be performed

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169 rapidly.

170 A non-selective alpha-blocker can be given as antidote. If required, initiate fever lowering measures,
171 anticonvulsive therapy and oxygen ventilation.

172 Vasopressors are contraindicated.

173

174 **5 PHARMACOLOGICAL PROPERTIES**

175 **5.1 Pharmacodynamic properties**

176 Pharmacotherapeutic group: Sympathomimetics, plain.

177 ATC code: R01AA05

178 Category and class: **A.16.1 Nasal Decongestants**

179 Oxymetazoline is a direct-acting sympathomimetic amine. It acts on alpha-adrenergic receptors in the
180 arterioles of the nasal mucosa to produce constriction, resulting in decreased blood flow and
181 decreased nasal congestion.

182 Application of oxymetazoline into the nostrils leads to decongestion of the inflamed nasal mucosa and
183 thus to a normalization of nasal breathing.

184

185 **5.2 Pharmacokinetic properties**

186 *Absorption*

187 The effect of oxymetazoline sets in within a few minutes.

188 The effect of oxymetazoline persists for up to 12 hours.

189 Relevant absorption of pharmacodynamically effective doses of oxymetazoline following the
190 recommended topical use is regarded as uncommon but cannot be excluded.

191 The absorption rate is estimated at 3,5 hours. The maximum plasma concentration can be found after
192 8 to 10 hours.

193 ***Elimination***

194 Terminal serum half-life is 35 hours, and the excretion measured in faeces (1,1 % of the applied dose,
195 after 48 hours) and urine (2,1 % of the applied dose, after 96 hours).

196

197 **6 PHARMACEUTICAL PARTICULARS**

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198 **6.1 List of excipients**

199 Sorbitol

200 Sodium citrate dihydrate (for pH-adjustment)

201 Polysorbate 80

202 Benzyl alcohol

203 Citric acid, anhydrous (for pH-adjustment)

204 Benzalkonium chloride solution

205 Acesulfame potassium

206 Levomenthol

207 Cineole (eucalyptol)

208 Disodium edetate

209 Aloe dry extract

210 Levocavone

211 Water, purified.

212

213 **6.2 Incompatibilities**

214 Not applicable

215

216 **6.3 Shelf life**

217 Glass bottle 15 ml: 3 years

218 Use within 12 months of first opening the bottle.

219

220 **6.4 Special precautions for storage**

221 Store at or below 25 °C.

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222 Protect from light. Keep well closed.

223

224 **6.5 Nature and contents of container**

225 15 ml Brown glass bottle with a metering pump (polypropylene).

226

227 **6.6 Special precautions for disposal**

228 No special requirements.

229

230 **7 HOLDER OF CERTIFICATE OF REGISTRATION**

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

232 10 th Floor, Alice Lane Towers, 15 Alice Lane

233 Sandton, 2196

234 South Africa

235

236 **8 REGISTRATION NUMBER(S)**

237 50/16.1/0335

238

239 **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

240 20 September 2022

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