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 hypersensive (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

Take special care with iliadin Aloe

- If you are taking (or have taken during the last two weeks) monoamine oxidase inhibitors (MAO inhibitors) or tricyclic antidepressants (used in the treatment of depression), antiparkinson's medicines such as bromocriptine (used in the treatment of Parkinsons's disease).
- Medicines that potentially increase blood pressure.
- If you suffer from increased eyeball-pressure (narrow-angle glaucoma).

- If you suffer from severe heart diseases (e.g. coronary heart disease,angina, high blood pressure, cardiac asthma).
- If you suffer from phaeochromocytoma (tumor of adrenal gland tissue i.e. chromaffin cells)
- If you suffer from metabolic disorders (e.g. overactive thyroid, diabetes mellitus, porphyria).
- If you have enlargement of the prostate.

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

Do not exceed the recommended dose.

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

The effect of **iliadin Aloe** may be reduced withlong-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 the tissue that lines the nose and the bone underneath to shrink down, causing blocked nose, swelling and irritation inside the nose.

Rebound effects and reduced effect 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.

Other medicines and iliadin Aloe

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

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

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

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

- Medicines used for the treatment of high blood pressure.
- Medicines used to teat Parkinsons disease e.g. bromocriptine.

Pregnancy, breastfeeding and fertility

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

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

Driving and using machines

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

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

3. How to take iliadin Aloe

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

Always take iliadin Aloe exactly as your heathcare provider has told you. Check with your health care provider if you are unsure.

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

The usual dose is:

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

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

Children under 6 years: Do not use.

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

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

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

Method of administration

iliadin Aloe

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



If you take more iliadin Aloe than you should

Overdosage may occur after nasal or accidental oral administration

Symptoms of an overdose may be:

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

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

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take iliadin Aloe

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

4. Possible side effects

iliadin Aloe can have side effects.

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

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

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing, rash or itching.
- Fits or seizures.
- Fainting

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

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

- Fast, irregular or pounding heartbeat
- High blood pressure

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

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

The following side effects have been frequently reported:

- Aqueous nasal secretions (runny nose), crusted nose.

The following side effects have been reported less frequently:

- Rebound congestion (increase in runny or stuffy nose).
- Headache or light-headedness, nervousness, trembling.
- Nausea

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

- Nasal discomfort (burning of the nasal mucosa), nasal dryness and sneezing, swelling of the lining of the nasal mucosa, bleeding from the nostril, throat discomfort.
- Drowsiness, sleep or calm induced by medication, hallucinations, tremor, anxiety, restlessness, irritabilty, 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 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

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

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

The other ingredients are:

Sorbitol

Sodium citrate dihydrate (for pH-adjustment)

Polysorbate 80

Citric acid, anhydrous (for pH-adjustment)

Levomenthol

Cineole (eucalypthol)

Disodium edetate

Aloe dry extract

Levocarvone

Water, purified.

What iliadin Aloe looks like and contents of the pack

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

Holder of certificate of registration

P&G South African Trading (Pty) Ltd.

10th Floor, Alice Lane Towers, 15 Alice Lane

Sandton, 2196

South Africa

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Registration numbers

20 September 2022

Professional information may be accessed at:
https://www.iliadin.com/en_ZA/home/products-information.html