

Oxymetazoline / 0.05% Decongestant Nasal Drops

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What Iliadin 0.05% Decongestant Nasal Drops is used for

Acute and allergic rhinitis; inflammation of sinus cavity, inflammation of the auditory tube and to relieve symptoms associated with the infection of the middle ear. Diagnostic decongestion of mucous membrane.

How Iliadin 0.05% Decongestant Nasal Drops works

The active ingredient of Iliadin 0.05% has a decongestant effect on the mucous membrane. The application of 0.05% decongestant nasal drops into the nostrils leads to decongestion of the inflamed nasal mucosa and thus to normalization of nasal breathing. Also, decongestion of the nasal mucosa opens the ducts of the sinuses and clears the auditory tube. This facilitates the discharge of secretion and combats bacterial invasion. The effect of 0.05% oxymetazoline sets in within a few seconds. The effect of oxymetazoline persists for up to 12 hours.

Before you use Iliadin 0.05% Decongestant Nasal Drops

- When you must not use it
 - -If you suffer from a form of rhinitis in which the mucous membrane of the nose is abnormally dry (rhinitis sicca). -Hypersensitivity to the active ingredient or to any of the excipients.

-Infants and small children below six years of age.

• Before you start use it

In the following cases this drug may only be used after carefully weighing the risk-to-benefit ratio:

- Patients treated with drugs that can potentially increase blood pressure.
- Increased pressure in the eyes, especially narrow-angle glaucoma.
- Severe heart diseases (e.g. coronary heart disease, hypertension).
- Tumour of the adrenal gland (Phaeochromocytoma)
- Hyperthyroidism
- Diabetes
- Enlargement of prostate

• Taking other medicines

The concomitant use of oxymetazoline containing nasal drops/nasal spray and medicine with hypertensive effect may lead to an increase in blood pressure due to their effect on the heart.

Overdosage or intake of the product and use of medicines with blood pressure increasing effect simultaneously or immediately prior to the administration can lead to an increase in blood pressure.

How to use Iliadin 0.05% Decongestant Nasal Drops

- How much to use
 Iliadin 0.05% Decongestant Nasal
 Drops is indicated for
 administration into the nose.
 Unless otherwise prescribed, instill
 1-2 drops of Iliadin 0.05%
 Decongestant Nasal Drops into each
 nostril 2-3 times daily.
 Iliadin 0.05% Decongestant Nasal
 Drops may only be administered to
 adults and children of 6 years and
 older and should not be used in
 small children and infants.
- When to use it
 Use as directed by your doctor or pharmacist.
- How long to use it

Iliadin 0.05% Decongestant Nasal Drops should not be used for longer than 10 consecutive days. Application for more than 10 consecutive days has to be prescribed by a physician. A treatment-free period of several days should precede any repeated use.

Long-term use and overdosage must be avoided, especially in children. Dosages higher than recommended may only be used under medical supervision.

• If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

• If you use too much (overdose)

Overdosage may occur after nasal or accidental oral administration. Symptoms of overdose may be: increase in blood pressure, increase in heart rate, palpitations, irregular heart beat, cardiac arrest, sweating, agitation, convulsion, dilation of pupil in the eye, nausea, vomiting, cyanosis, fever, spasms, circulatory collapse, build up of fluid in the lungs, respiratory disorders, psychic disorders, drowsiness, paleness, miosis, decrease in body temperature, decrease in heart rate, shock-like decrease in blood pressure and coma. In children, in particular, overdose can cause central nervous effects with convulsions and coma, decrease in heart rate, suspension of breathing as well as increase in blood pressure possibly followed by decrease in blood pressure. Visit your doctor or go to the nearest Emergency Department if you have used too much of this medication.

While you are using it

Things you must not do
 Long term use and overdosage are to be avoided as the efficacy of the medicine may decrease.

Abuse of decongestant rhinological agents may cause:



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- Rebound effect
- Chronic swelling of the nasal mucosa
- Reduction in mucosal tissue
- Abnormal dryness of mucosa Medical supervision is indicated in patients with chronic rhinitis. Dosages higher than recommended may only be used under medical supervision.
- Things to be careful of

Iliadin 0.05% Decongestant Nasal Drops should only be used after the consultation with a physician during pregnancy and lactation. The recommended dosage must not be exceeded.

Side effects

Adverse events are infrequent and rare. Events include: burning sensation of the nasal mucosa, nasal dryness, sneezing (especially in sensitive patients). After the effect has worn off, increased swelling of the mucosa, bleeding from the nose, somnolence, sedation, headache, palpitations, increased heart beat, hypertension, hypersensitivity reactions, insomnia, restlessness, and fatigue.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and Disposal of Iliadin 0.05% Decongestant Nasal Drops

- Storage

Do not store above 25°C Keep out of reach of children. After opening the pack, Iliadin 0.05% Decongestant Nasal Drops should not be used longer than 6 months.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like Clear, colourless solution

- Ingredients

- Active ingredient 1ml Iliadin 0.05% contains 0.5mg oxymetazoline hydrochloride
- Inactive ingredients
 Citric acid monohydrate,
 benzalkonium chloride solution
 50% (as a preservative), sodium
 citrate, glycerol 85%, purified
 water.
- <u>MAL number:</u> MAL19870787A

Manufacturer

Merck KGaA, Frankfurter Str. 250, D-64293 Darmstadt, Germany

Product Registration Holder

Merck (M) Sdn Bhd (178145-V) Level 3, Menara Sunway Annexe, Jalan Lagoon Timur, Bandar Sunway, 46150 Petaling Jaya, Selangor, Malaysia

Date of revision

19 July 2013