

iliadin[®]

0.01% Decongestant Nasal Drops

Dear Patient,

Please read the following instructions for use carefully, for they contain important information about what you should pay attention to when using this medication. If you have any questions please consult your doctor or pharmacist.

Instructions for use



**Iliadin 0.01%
Decongestant
Nasal Drops
for infants**

Product registrant

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Composition of drug

1ml Iliadin 0.01% Decongestant Nasal Drops contains in an aqueous solution 0.1mg Oxymetazoline Hydrochloride.

Description

Clear, colourless solution.

Excipients

Citric acid monohydrate, benzalkonium chloride, sodium citrate, glycerol 85%, purified water.

Expiry date

Please note the expiry date on the package. The drug should not be used after the expiry date has elapsed. After opening the pack, Iliadin 0.01% Decongestant Nasal Drops should not be used longer than 6 months.

Storage conditions

Store at or below 30°C.
Keep medicament out of reach of children.

Indications

Acute cold, paranasal sinusitis, syringitis, otitis media.

Dosage, mode of administration



Iliadin 0.01% Decongestant Nasal Drops is intended for intranasal application. Unless otherwise prescribed, up to the age of 4 weeks instill 1 drop of Iliadin 0.01% Decongestant Nasal Drops into each nostril 2-3 times daily. From the 5th week of life until the age of 1 year, instill 1-2 drops of Iliadin 0.01% Decongestant Nasal Drops into each nostril 2-3 times daily. To facilitate and ensure exact dosing, Iliadin 0.01% Decongestant Nasal Drops is supplied with a metering pipette. The numbers on the markings indicate the quantity of drops drawn up. For example if 1 drop is to be administered, the liquid level should be at mark 1 when filling the pipette. This ensures that exactly the desired dose is dripped into the nostrils. The following procedure has also proved efficient: Depending on the age of the infant, drip 1 or 2 drops of Iliadin 0.01% Decongestant Nasal Drops onto cotton wool to wipe out the nostrils.

Interactions

The concomitant use of oxymetazoline containing nasal drops and of medicines with a hypertensive effect (e.g. MAO-inhibitors and tricyclic antidepressants) may lead to an increase in blood pressure due to their cardiovascular activity.

Overdose or swallowing of Iliadin 0.01% Decongestant Nasal Drops and use of tricyclic antidepressants or MAO-inhibitors simultaneously or immediately prior to administration of Iliadin 0.01% Decongestant Nasal Drops can lead to an increase blood pressure.

Duration of treatment

Unless specifically prescribed by the doctor, Iliadin 0.01% Decongestant Nasal Drops should only be used for short periods of time (5-7 days). Application for more than 7 consecutive days has to be prescribed by a physician. A treatment-free period of several days should precede any repeated use.

Permanent use of decongestant rhinological agents may attenuate their effect. The abuse of local rhinological agents may cause mucosal atrophy and reactive hyperaemia with rhinitis medicamentosa.

Longer use of oxymetazoline may cause damage to the mucosal epithelium with inhibition of ciliary activity. This may possibly result in irreversible damage to the mucosa with rhinitis sicca.

Long term use and overdose are to be avoided, especially in children. Special attention should be paid during application to avoid overdose. Medical supervision is indicated in premature or underweight newborns to avoid the risk of overdose. Medical supervision is indicated in patients with chronic rhinitis. Dosage higher than recommended may only be used under medical supervision.

Precautions for use

Iliadin 0.01% Decongestant Nasal Drops should only be used after the consultation with a physician during pregnancy and lactation. The recommended dosage must not be exceeded.

Pharmacotherapeutic group

Rhinological agents (chemically defined), α -sympathomimetic.

The active ingredient of Iliadin 0.01% Decongestant Nasal Drops has a sympathomimetic, vasoconstrictive, and thus a decongestant effect on the mucous membranes.

The action of Iliadin 0.01% Decongestant Nasal Drops sets in within a few minutes, but may take up to 20 minutes for an observed effect. The effect of oxymetazoline persists for up to 12 hours.

Side effect

Occasionally, burning or dryness of the nasal mucosa, sneezing. In rare cases after the effect has worn off an intense sensation of "blocked" nose (reactive hyperaemia). With topical intranasal use, overdose leads occasionally to systemic sympathomimetic effects like palpitations, accelerated pulse (tachycardia) and increase in blood pressure. Restlessness, insomnia, tiredness and headaches have been observed in very rare cases. Epistaxis, apnoea in newborns and in young infants (especially in case of overdose), hallucinations and convulsions. Effects on the ability to drive a vehicle or operate machinery: Systemic effects with cardiovascular involvement cannot be excluded after prolonged administration or intake of oxymetazoline-containing cold remedies in doses higher than recommended. In these cases the ability to drive a vehicle or operate machinery can be impaired.

Contraindications

Rhinitis sicca, hypersensitivity to the active ingredients or to any of the excipients.

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

- Patients treated with monamine oxidase inhibitors (MAO-inhibitors) and other drugs potentially increasing blood pressure
- Increased intraocular pressure, especially narrow-angle glaucoma
- Severe cardiovascular diseases (e.g. coronary heart disease, hypertension)
- Pheochromocytoma
- Metabolic disorders (eg. hyperthyroidism, diabetes mellitus, porphyria)
- Hyperplasia of the prostate

Because of the benzalkonium chloride which is contained as preservative, Iliadin 0.01% Decongestant Nasal Drops must not be used in known hypersensitivity to this substance.

Overdose

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

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

Therapeutic measure after overdose:

- In-house intensive-care therapy is indicated in cases of severe overdose.
- Administration of medicinal charcoal (absorbent), sodium sulfate (laxative) or gastric lavage (in the case of large quantities) should be performed immediately as oxymetazoline may be absorbed rapidly.
- A non-selective alpha blocker can be given as antidote. If required, initiate fever-lowering measures, anticonvulsive therapy and oxygen ventilation.

Vasopressors are contraindicated.

Symptoms of an overdose may be hypertension, tachycardia, palpitations, cardiac arrhythmia, cardiac arrest, sweating, agitation, convulsion, mydriasis, nausea, vomiting, cyanosis, fever, spasms, circulatory collapse, pulmonary oedema, respiratory and psychic disorders, drowsiness, paleness, miosis, decrease in body temperature, bradycardia, shock-like hypotension, apnoea and coma.

Presentation and package size

Iliadin 0.05% aqueous solution for adults and children of school age: 10ml pipette bottle or 10ml spray bottle.

Iliadin 0.025% aqueous solution for small children: 10ml pipette bottle

Iliadin 0.01% aqueous solution for infants: 5ml pipette bottle or 5ml metered drop (preservative free).

Availability of some presentations may be subjected to local variation

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