7873110223/MAL2362

iliadin®

0.05% 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 0.05% Decongestant Nasal Drops for adults and school children of 6 years and older

Composition of drug
1ml Iliadin 0.05% Decongestant Nasal Drops contains in an aqueous solution 0.5mg Oxymetazoline Hydrochloride

Description
Clear, colourless solution

Excipients
Citric acid monohydrate, benzalkonium chloride solution 50% (as a preservative), 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 0.05% 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

Marketing authorization holder
For Malaysia:
Procter & Gamble (Malaysia) Sdn Bhd (8842-P),
10th Floor, Surian Tower,
1, Jalan PJU 7/3, Mutiara Damansara,
47810 Petaling Jaya,
Selangor Darul Ehsan, Malaysia
For Singapore:
Procter & Gamble (Singapore) Pte Ltd,
11, North Buona Vista Drive,
#21-07 The Metropolis Tower 2,
138589 Singapore

Manufacturer
Merck Healthcare KGaA,
Frankfurter Strasse 250,
64293 Darmstadt,
Germany

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June 2019

Indications
Acute cold, paranasal sinusitis, syringitis, otitis media.

Dosage, mode of administration

Iliadin 0.05% Decongestant Nasal Drops is intended for intranasal application. 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.

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 0.05% Decongestant Nasal Drops and use of tricyclic antidepressants or MAO inhibitors simultaneously or immediately prior to administration of Iliadin 0.05% Decongestant Nasal Drops can lead to an increase blood pressure.

Duration of treatment
Unless specifically prescribed by the doctor, Iliadin 0.05% Decongestant Nasal Drops should only be used for short periods of time (up to 10 days). 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 overdosage must be avoided, especially in children. Medical supervision is indicated in patients with chronic rhinitis. Dosage higher than recommended may only be used under supervision.

Precautions for use
In the following cases this drug may only be used after carefully weighing the risk-to benefit ratio:
- Patients treated with monoamine oxidase inhibitors (MAO inhibitors, tricyclic antidepressants) and other drugs potentially increasing blood pressure.
- Increased intraocular pressure, especially narrow-angle glaucoma.
- Severe cardiovascular diseases (e.g. coronary heart disease, hypertension).
- Phaeochromocytoma.
- Metabolic disorders (e.g. hyperthyroidism, diabetes mellitus, porphyria).
- Hyperplasia of the prostate.

Long-term use and overdosage are to be avoided. The efficacy of decongestant rhinological agents 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 the product is discontinued. Patients are advised to use for a maximum of 10 consecutive days to avoid rebound effect and drug induced rhinitis.

Medical supervision is indicated in patients with chronic rhinitis. Dosages higher than recommended may only be used under medical supervision.

Benzalkonium chloride: irritant, may cause skin reactions.

Pharmacotherapeutic group
Rhinological agents (chemically defined), α-sympathomimetic. The active ingredient of Iliadin 0.05% Decongestant Nasal Drops has a sympathomimetic, vasoconstrictive, and thus a decongestant effect on the mucous membranes.

The effect of Iliadin 0.05% Decongestant Nasal Drops sets in within few seconds. In a clinical study, the median onset was found to be 25 seconds. The effect persists for up to 12 hours.

Undesirable effects
Adverse events from clinical trial data are both infrequent and based on small patient exposure. Accordingly, events reported from extensive post-marketing experience at therapeutic/recommended dose and considered attributable are listed below. As most undesirable effects are based on post-marketing spontaneous reporting, precise frequency estimation is not possible.

Respiratory, thoracic and mediastinal disorders: nasal discomfort (burning of the nasal mucosa), nasal dryness, sneezing (especially in sensitive patients), after the effect has worn off increased swelling of the mucosa (reactive hyperaemia) & epistaxis.

Nervous system disorders: somnolence, sedation, headache, hallucinations (especially in children) & convulsions (especially in children).

Cardiac disorders: palpitations & tachycardia.

Vascular disorders: hypertension.

Immune system disorders: hypersensitivity reactions (angioedema, rash, pruritus).

Psychiatric disorders: insomnia & restlessness.

General disorders and administration site conditions: fatigue & tachyphylaxis (associated with long-term use or overdose).

Effects on ability to drive and use machines
No impairment is to be expected if used as recommended. Systemic effects with involvement of the cardiovascular or central nervous system cannot be excluded after prolonged administration or intake of oxymetazoline containing cold remedies in dose higher than recommended. In these cases the ability to drive a vehicle or operate machinery can be impaired.

Fertility, pregnancy and lactation
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.

Overdose
- Overdosage may occur after nasal or accidental oral administration. 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.

  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.

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

- Therapeutic measure after overdosage: 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.

Contraindications
Rhinitis sicca, hypersensitivity to the active ingredient or to any of the excipients, children below six years of age.

Because of the benzalkonium chloride which is contained as preservative Iliadin 0.05% Decongestant Nasal Drops must not be used in known hypersensitivity to this substance.

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 metered drop (preservative free).

Availability of some presentations may be subjected to local variation

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