CONFIDENTIAL PROPERTY OF PROCTER & GAMBLE
IMPORTANT: This drawing print is loaned for mutual assistance and as subject to recall at any time. Information contained herein is not to be disclosed or reproduced in any form or benefit of parties other than necessary subcontractors and suppliers without written consent of Procter & Gamble.

BUSINESS USE

Drawing #: ILST-00066994 001

DESCRIPTION: LEAFLET CUT 210x296mm

INFORMATION: Open Field for Blueprint Description
-

DATE: 31/08/2021

DRAWN BY: Sourabh Ghatage

UNITS: mm | SIDE SHOWN: Outside

ArtiosCAD Standard: PG_MASTER_TITLE_BLOCK-ENOVIA.ARD

REVISION HISTORY:
31/08/2021 : Initial Construction

LEGEND

CUT LINE
CREASE/ FOLD LINE
PERFORATION
GLUE ASSIST
PARTIAL CUT/ SLIT SCORE
EMBOSS/DEBOSS
COATING
BLEED
COPY AREA
COPY FREE
Print Area TEXT / Brand Marking Ink, with Varnish or Coating
Non-Print Area No TEXT, No Brand Marking No Ink, No Varnish, No Coating
Non-Print Area No TEXT / No Brand Marking No Ink, with Varnish or Coating
Print Area (Background Color) No TEXT / No Brand Marking Ink, with Varnish or Coating
Print Area (Background Color) No TEXT / No Brand Marking Ink, No Varnish, No Coating
Glue Pattern / Panel No Ink, No Varnish, No Coating

12mm

210mm

Preservative Free

iliadin®

0.01% Decongestant Nasal Drops

New Metered Dropper System

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

Composition of drug
100 ml Iliadin 0.01% metered drops contains 0.01g Oxymetazoline Hydrochloride in aqueous solution.

Product description
Almost clear solution, not more strongly coloured than colour reference solution Y7.

Dosage form
0.01% decongestant nasal drops: 3k dropper pump with 5 ml, N1.

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% nasal drop should not be used longer than 6 months.

Special notes on storage
Do not store above 30 °C.

Packaging
External container and bottle polypropylene, inliner: polyethylene. 3k dropper pump with 5 ml.

Product Registration Holder
Procter & Gamble (Malaysia) Sdn Bhd,
10th Floor, Surian Tower,
1, Jalan PJU 7/3, Mutiara Damansara,
47810 Petaling Jaya, Selangor Darul Ehsan, Malaysia

Name and address of manufacturer
FAMAR Health Care Services Madrid, S.A.U,
Avda, Leganes, 62
Alcorcon 28923 (Madrid)
Spain

Date of issue
June 2019

Indications
Acute rhinitis, vasomotor rhinitis, allergic rhinitis, paranasal sinusitis, syringitis. For diagnostic decongestion of mucous membranes.

Dosage, mode and duration of use
Infants:
Up to the age of 4 weeks instill 1 drop of the 0.01% solution into each nostril 2-3 times daily. From the 5th week of life until the age of 1 year, instill 1-2 drops into each nostril 2-3 times daily.

Instill the solution into each nostril. As the metered dropper bottle must be held in an upside-down position for application, Iliadin metered drops for infants can only be applied with the baby's head bent backwards.

Especially in the case of the 0.01% solution for infants 20 minutes may elapse before the onset of action.

0.01% decongestant nasal drops are intended for application in the nose only.

The single doses given for 0.01% decongestant nasal drops must not be administered more than 3 times daily.

A treatment-free period of several days should precede any repeated use.

Without medical prescription, 0.01% decongestant nasal drops should not be used for longer than 10 consecutive days.

Contraindications
Rhinitis sicca, hypersensitivity to the active ingredient or one of the other ingredients.

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) 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).

Medical supervision is indicated in premature or underweight newborns to avoid the risk of overdosage.

Medical supervision is indicated in patients with chronic rhinitis.

Precautions for use and warnings
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. Dosages higher than recommended may only be used under medical supervision.

As with all nasal decongestant, Iliadin should not be used for longer than 10 consecutive days.

1150615-00

296mm

41

10mm

189.1mm

12mm

210mm

SAW001347
1150615-00

iliadin®

0.01% Decongestant Nasal Drops

Drug interactions and other interactions

No interactions with tricyclic antidepressants or monoamine oxidase inhibitors of the tranylcypromine type have been reported in the recommended dosage of 0.01% decongestant nasal drops. Overdosage or swallowing of 0.01% decongestant nasal drops and use of tricyclic antidepressants or MAO-inhibitors simultaneously or immediately prior to administration of Iliadin can lead to an increase in blood pressure.

Use during pregnancy and lactation

During pregnancy and lactation the recommended dosage should not be exceeded, since overdosage can impair the blood supply to the unborn child or reduce milk production. As a precaution, the doctor should be consulted prior to using the preparation and the risk-to-benefit ratio must be carefully weighed.

Effects on the ability to drive a vehicle or to 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.

Adverse reactions

In especially sensitive patients, burning or dryness of the nasal mucosa, or sneezing may occasionally occur.
In rare cases - after the effect has worn off - an intense sensation of "blocked" nose (reactive hyperaemia).

With topical intranasal use, overdosage leads rarely to 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.

Overdosage

- Emergency measures, symptoms and antidotes

After overdosage or accidental oral ingestion the following symptoms may occur: Mydriasis, nausea, vomiting, cyanosis, fever, spasms, tachycardia, cardiac arrhythmia, circulatory collapse, cardiac arrest, hypertension, pulmonary oedema, respiratory disorders, psychic disorders. Furthermore, inhibition of central-nervous functions with drowsiness, decrease in body temperature, bradycardia, shock-like hypotension, apnoea and coma can possibly also develop.

Therapeutic measures to be taken after overdosage Administration of medicinal charcoal, gastric lavage, oxygen ventilation. To lower the blood pressure, phentolamine 5 mg in saline solution slowly i.v. or 100 mg orally. Vasopressors are contraindicated. If required, lowering of fever and anticonvulsive therapy.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties
- Substance or indication group
Rhinological agents (chemically defined), a-sympathomimetic

Oxymetazoline has a sympathomimetic, vasoconstrictive and therefore a decongestant effect on mucous membranes. The application of 0.01% decongestant nasal drops metered drops/0.025% decongestant nasal drops after 0.01% decongestion of the nostrils decongests the inflamed nasal mucosa and causes excessive secretion to stop. The patient is able to breathe freely through the nose again. Also, decongestion of the nasal mucosa opens and dilates the efferent ducts of the paranasal sinuses and clears the auditory tube. This facilitates the discharge of secretion and combats bacterial invasion.

Pharmacokinetic properties
Investigations with radiolabelled oxymetazoline in healthy volunteers revealed that this intranasally applied rhinological agent has no systemic effect. Oral administration (double-blind studies) showed first unspecific ECG changes only after administration of 1.8 mg oxymetazoline - this is equivalent to 3.6 ml of a 0.05 % solution. Neither blood pressure nor pulse rate were affected by the intake of this quantity of active substance.

After intranasal application of doses higher than recommended the absorbed quantity can suffice to trigger systemic effects in the cardiovascular system. In rare cases the quantity absorbed after intranasal application can suffice to produce systemic effects in the central nervous system (cf.adverse reactions).

The half-life of terminal elimination after nasal application is 35 hours in humans. 2.1 % is excreted via the kidneys and about 1.1 % via the faeces.

No information is available on the distribution of oxymetazoline in humans.

Preclinical safety data

- Acute toxicity
The LD50 of oxymetazoline hydrochloride was established as 0.9 mg/kg (i.v.) and 1.3 mg/kg (oral) in rats. Mice showed an LD50 of 9.2 mg/kg (i.v.)
and 26 mg/kg (oral). Symptoms of acute intoxication included piloerection, exophthalmos, mydriasis and nosebleeds. At higher doses pallor, mild cyanosis and reduced motility were observed. In terminal conditions asphyctic convulsions occurred.

0.01% decongestant nasal drops for infants the 0.01% solution into each nostril 2-3 times daily. From the 5th week of life until the age of 1 year, instill 1-2 drops into each nostril 2-3 times daily.

0.01% decongestant nasal drops are intended for application in the nose only.

The single doses given for 0.01% decongestant nasal drops must not be administered more than 3 times daily.

A treatment-free period of several days should precede any repeated use.

Without medical prescription, 0.01% decongestant nasal drops should not be used for longer than 10 consecutive days.

Incompatibilities
Incompatibilities are unknown to date.

- Subacute toxicity
0.6 ml of an 0.05 % solution (0.3 mg oxymetazoline hydrochloride) - instilled into each nostril 3 times daily for 13 weeks - was well tolerated by dogs. No toxic effects, systematically or in the nasal mucosa, occurred. No significant changes in the ECG or in the eyes were observed. The doses investigated amounted to up to 60 times the dosage recommended for humans.

- Chronic toxicity
Dogs received nasal doses of 0.06 ml and 0.24 ml of 0.05 % oxymetazoline hydrochloride solution twice daily for 1 year. No toxic effects developed. The doses investigated amounted to up to three times the dosage recommended for humans.

- Reproduction toxicology
Reproduction in rats: Subcutaneous administration of 0.08 mg/kg and 0.24 mg/kg oxymetazoline from the 6th and 15th postcoital day did not cause any somatic abnormalities in the offspring. A slight difference in the number of resorptions was not statistically significant. The doses investigated amounted to up to 25 times and 75 times, respectively, the dosage recommended for humans.

- Mutagenic and tumorigenic potential
No data are available on mutagenesis and carcinogenesis.

1150615-00

296mm

SUB

Veeva Vault No: SAW001347
PMP/IPMS: 1150615-00
MPMP: N/A
POA Description: SAW001347-Iliadin Infant 0.01% (PIL) MY

Supplier Ref: 402529200_r3 **Date:** 14-May-2026

PMS 3265 C 0|5 | Black 0|5

REPRESENTATION: Colours represented with a diagonal line have been modified to aid PDF approval.

Fonts:
MetaPro-Medi RotisSansSerif
MyriadPro-Regular RotisSansSerif-Italic
RotisSansSerif-ExtraBold
RotisSansSerif-Bold
Body Copy: 13 pt
Min font size used: 7 pt

Region: ASEAN/A/I
Manf. Plant: Famar Madrid
Substrate: OFFSET WHITE PAPER
Printer: Famar Madrid
Laetus: 209
Colour Correct: Yes

Technical Drawing: ILST-00066994.001 (5.69x 21.69x 1)

PHC International

OVERPRINT PREVIEW
OFF VIEW CONTENT

SGK is a Matthews International Corporation