SCHEDULING STATUS: **S1**

PROPRIETARY NAME AND DOSAGE FORM:

ILIADIN® BABY NOSE DROPS

Nose Drops

COMPOSITION:

Each 1 ml of the solution contains:

0,100 mg/0,01 % Oxymetazoline Hydrochloride

0,005 % *m/v* Benzalkonium Chloride as preservative

PHARMACOLOGICAL CLASSIFICATION:

A.16.1 Nasal Decongestants

PHARMACOLOGICAL ACTION:

Oxymetazoline is a direct-acting sympathomimetic amine. It acts on alpha-adrenergic receptors in the arterioles of the nasal mucosa to produce constriction, resulting in decreased blood flow and decreased nasal congestion.

INDICATIONS:

ILIADIN® BABY NOSE DROPS is indicated for the short term (< 5 days) treatment of nasal congestion associated with acute rhinitis in infants older than one month of age.

CONTRAINDICATIONS:

Hypersensitivity to any of the ingredients, including benzalkonium chloride.

Porphyria.

WARNINGS AND SPECIAL PRECAUTIONS:

Never use **ILIADIN® BABY NOSE DROPS** more frequently than recommended.

Do not administer for prolonged periods without the advice of a medical practitioner.

Insufficient evidence to establish safety and efficacy in infants less than one month of age.

In the following cases, **ILIADIN® BABY NOSE DROPS** 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).

INTERACTIONS:

Since **ILIADIN® BABY NOSE DROPS** is absorbed through the mucosa, interactions may follow topical application. All sympathomimetic nasal decongestants are liable to cause a hypertensive crisis if used during treatment with a MAOI. Also, if significant absorption of **ILIADIN® BABY NOSE DROPS** occurs, concurrent use of maprotiline may potentiate the pressor effect of the oxymetazoline.

PREGNANCY AND LACTATION:

During pregnancy and lactation the recommended dosage should not be exceeded and the preparation should only be used after carefully weighing the risk-to-benefit ratio.

DOSAGE AND DIRECTIONS FOR USE:

Do not administer for longer than 5 days. Do not exceed the recommended dosage.

If symptoms persist, consult a medical practitioner.

Infants (1 to 12 months of age):

Instil 1-2 drops into each nostril 2-3 times a day.

To facilitate and ensure exact dosing, **ILIADIN® BABY NOSE DROPS** is supplied with a pipette.

Hold the head well back and to the side when instilling the drops.



SIDE EFFECTS:

Nasal Mucosa:

Common (≥ 1 % and < 10 %): Burning, dryness or stinging of nasal mucosa and sneezing.

Rare (≥ 0,1 % and < 1 %): Rebound congestion (increase in runny or stuffy nose).

Heart and Circulatory System:

Rare (≥ 0,1 % and < 1 %): Fast, irregular or pounding heartbeat.

Central Nervous System:

Single cases: (< 0,01 %): Headache or light-headedness, nervousness, trembling and trouble in sleeping.

Systemic effects have occurred after local administration.

If unexpected side effects appear, consult your medical practitioner immediately.

Children may be especially prone to systemic absorption of **ILIADIN® BABY NOSE DROPS** with resulting side/adverse effects.

KNOWN SYMPTOMS OF OVER DOSAGE AND PARTICULARS OF ITS TREATMENT:

See **SIDE EFFECTS.**

Local gastric irritation and possible systemic sympathomimetic effects may occur, e.g. sweating, tachycardia, drowsiness possibly leading to coma, convulsions and circulatory collapse.

Treatment should be symptomatic and supportive.

IDENTIFICATION:

Clear, colourless solution with a faint odour.

PRESENTATION:

5 ml Nose Drops (amber glass dropper bottle).

STORAGE INSTRUCTIONS:

Store at or below 25 ˚C.

Protect from light.

Keep out of reach of children.

REGISTRATION NUMBER:

34/16.1/0366

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

P&G South African Trading (Pty) Ltd.[1]

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