SCHEDULING STATUS: **S1**

PROPRIETARY NAME AND DOSAGE FORM:

Iliadin® Nose Drops 0,05 % (nose drops)

Iliadin® Nose Spray 0,05 % (nasal spray or metered spray)

COMPOSITION:

Each 1 ml of the solution contains:

0,5 mg/0,05 % *m/v* Oxymetazoline Hydrochloride

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

PHARMACOLOGICAL CLASSIFICATION:

A.16.1 - Nasal Decongestants

PHARMACOLOGICAL ACTION:

Iliadin® Nose Drops/Metered Nose Spray/Nose Spray is a topical vasoconstrictor, which exerts a decongestant action on mucous membranes of the nasopharyngeal cavity.

INDICATIONS:

Iliadin® Nose Drops/Metered Nose Spray/Nose Spray is indicated for the relief of nasal congestion due to the common cold, sinusitis, allergic rhinitis and hay-fever.

Indicated as adjunctive treatment in middle ear infection.

CONTRAINDICATIONS:

Hypersensitivity to any of the ingredients.

WARNINGS AND SPECIAL PRECAUTIONS:

Iliadin® Nose Drops/Metered Nose Spray/Nose Spray should be used with care in patients with cardiac disease, hypertension or hyperthyroidism.

Iliadin® Nose Drops/Metered Nose Spray/Nose Spray should not be used for a period longer than five days. Prolonged use may cause rebound congestion and drug-induced rhinitis.

It is not advisable to use **Iliadin® Nose Drops/Metered Nose Spray/Nose Spray** more frequently than recommended.

INTERACTIONS:

None Known.

PREGNANCY AND LACTATION:

Safety and efficacy in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE:

Iliadin® Nose Drops/Metered Nose Spray/Nose Spray are indicated for adults and children aged six years and older.

Nose Drops:

Two to three drops into each nostril 2 – 3 times a day. See diagrams for directions for use.

Metered Nose Spray:

Two to three sprays into each nostril 2 – 3 times a day. See diagrams for directions for use.

Nose Spray:

One spray into each nostril 2 – 3 times a day. See diagrams for directions for use.

SIDE EFFECTS:

Iliadin® Nose Drops/Metered Nose Spray/Nose Spray may cause local stinging or burning, sneezing and dryness of the mouth and throat.

If unexpected side effects appear, consult your doctor immediately.

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 maximum of a faint odour.

PRESENTATION:

10 ml Nose Drops (dropper bottle).

10 ml Metered Nose Spray (bottle).

20 ml Nose Spray (plastic bottle).

STORAGE INSTRUCTIONS:

Store at or below 25 ˚C.

Protect from light.

Keep out of reach of children.

REGISTRATION NUMBERS:

Iliadin® Nose Drops: H1400 (Act 101/1965)

Iliadin® Nose Spray (nasal spray or metered): H1597 (Act 101/1965)

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

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

12th Floor, Alice Lane Towers, 15 Alice Lane

Sandton, 2196

South Africa

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

8 July 1988

[1] = Company Registration Number: 1989/004241/07

®= Registered Trademark

Namibia	NS1	Nose Drops 14/16.1/0119 Metered Nose Spray 14/16.1/0525 Nose Spray 14/16.1/0525
Botswana	S3	Nose Drops B9306405 Metered Nose Spray B9306410 Nose Spray B9306395

Iliadin® Nose Drops/Metered Nose Spray/Nose Spray

Directions for use

Nose Drops

Fill glass dropper unit by placing the open end into the liquid and depressing the rubber teat. Tilt the head back and instil 2- 3 drops of the liquid into each nostril.



Metered Nose Spray

For best results keep both the head and spray bottle in an upright position. Remove cap by pulling and insert the nozzle of the spray loosely into the nostril with the middle and forefinger around the bottom of the nozzle and the thumb on the base of the bottle. Depress the spray mechanism (as shown in the diagram) thus producing a fine mist. Sniff in to ensure an even distribution of the spray. Withdraw from nostril and release the spray mechanism. Repeat for the other nostril.



Nose Spray

Best results are obtained by keeping both the head and bottle in an upright position. Insert the nozzle of the spray loosely into the nostril and squeeze sharply,

while at the same time sniffing in to ensure an even distribution of the spray.

Withdraw the nozzle from the nostril, release the pressure and repeat the operation for the other nostril.

