1.3.1.1 Professional information for ENT NASAL DROPS

SCHEDULING STATUS:

S1

PROPRIETARY NAME AND DOSAGE FORM:

ENT NASAL DROPS

COMPOSITION:

Each 25 ml contains:

Phenylephrine hydrochloride	62,5 mg
Naphazoline nitrate	6,25 mg

List of excipients:

Alcohol, chlorbutol, nipasept, purified water and sodium chloride.

Preservatives:

Chlorbutol	0,5 % *m/v*
Nipasept	0,05 % *m/v*

CATEGORY AND CLASS:

A 16.1 Ear, nose and throat preparations. Nasal decongestants.

PHARMACOLOGICAL ACTION:

Vasoconstrictor for nasal decongestion.

INDICATIONS:

For the relief of nasal congestion due to colds, influenza, sinusitis, rhinitis, hay fever.

CONTRAINDICATIONS:

Severe coronary disease, hypertension, cardiovascular disease or hyperthyroidism. Patients being treated with monoamine oxidase inhibitors or within 14 days of stopping such treatment.

Pregnancy.

Sensitivity to any of the components.

WARNINGS AND SPECIAL PRECAUTIONS:

Not recommended for children under the age of two years.

Phenylephrine hydrochloride should be avoided or only used with great caution in patients susceptible to sympathomimetic effects particularly those with hyperthyroidism, cardiovascular disease such as ischaemic heart disease, arrhythmia or tachycardia, occlusive vascular disorders including arteriosclerosis, hypertension or aneurysms.

Excessive use can lead to rebound congestion as well as ventricular arrhythmias.

Naphazoline nitrate should be used with special caution in children. If used for more than a few days severe rebound congestion and rhinorrhoea may occur.

INTERACTIONS:

Phenylephrine hydrochloride should be avoided in patients receiving tricyclic antidepressants. Patients receiving guanethidine and similar adrenergic neurone blocking agents are extremely sensitive to the hypersensitive (and mydriatic) effects of phenylephrine. Phenylephrine may also markedly reverse the hypotensive effects of reserpine and methyldopa.

DOSAGE AND DIRECTIONS FOR USE:

Adults: 2 to 3 drops to each nostril.

Children: (3 to 12 years) 1 to 2 drops to each nostril.

Tilt the head back and instil the drops into each nostril. Then throw the head forward and down and maintain this position for at least 30 seconds. The first instillation prepares the way for deeper penetration by the second, which should be administered 2 to 3 minutes later. The effects will then last up to four hours, then the treatment may be repeated if necessary, but not more than three times daily.

SIDE EFFECTS:

Phenylephrine hydrochloride: May produce anxiety, restlessness, tremor, irritability and nausea and vomiting. Undesirably high blood pressure leading to cerebral haemorrhage may occur. Also reflex bradycardia, tachycardia, cardiac arrhythmias, anginal pain, palpitation and cardiac arrest; hypotension with dizziness, fainting and flushing

Naphazoline nitrate:

Transient irritation, nausea and headache may occur

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Naphazoline nitrate: Overdosage or accidental administration by mouth may cause depression of the central nervous system with marked reduction of body temperature and symptoms of bradycardia, sweating, drowsiness and coma, particularly in children. Hypertension may be followed by rebound hypotension.

High blood pressure and tachycardia can also occur.

Treatment is symptomatic and supportive. Consult a doctor or take the patient to the nearest hospital immediately.

IDENTIFICATION:

A clear, colourless liquid with an odour or chlorbutol.

PRESENTATION:

25 ml in an amber glass vial.

STORAGE INSTRUCTIONS:

Store in airtight containers at or below 30 °C and protect from light.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

H 1505 (Act 101/1965)

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

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