APPROVED PACKAGE INSERT

SCHEDULING STATUS

S1

SINUCON NASAL DROPS (nose drops)

COMPOSITION

Each 20 ml contains:

Naphazoline nitrate 5 mg

Phenylephrine HCl 50 mg

Chlorbutol 100 mg

Preservatives:

Methyl hydroxybenzoate sodium 0,03 % m/v

Propyl hydroxybenzoate 0,014 % m/v

Excipients:

Sodium chloride, sodium metabisulphite, disodium edetate, monobasic potassium phosphate, purified water.

PHARMACOLOGICAL CLASSIFICATION

A. 16.1 Decongestants.

PHARMACOLOGICAL ACTION

SINUCON NASAL DROPS causes vasoconstriction and has a rapid and prolonged action in reducing swelling and congestion when applied to mucous membranes.

INDICATIONS

Indicated for the relief of nasal congestion.

CONTRA-INDICATIONS

Contra-indicated in patients receiving treatment with mono-amine oxidase inhibitors. Should not be used in the presence of high blood pressure, thyrotoxicosis or patients with cardio-vascular disease:

WARNINGS AND SPECIAL PRECAUTIONS

Excessive or prolonged use may lead to rebound congestion or rhinorrhoea.

It should be used with special precaution in children.

DOSAGE AND DIRECTIONS FOR USE

2 drops in each nostril four hourly.

SIDE-EFFECTS

May cause transient irritation or nausea and headaches. Excessive or prolonged use may lead to rebound congestion or rhinorrhoea.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Refer 'SIDE-EFFECTS".

Accidental administration by mouth may cause symptoms of bradycardia, sweating, drowsiness and coma, particularly in children. Hypertension may be followed by rebound hypotension.

Treatment is symptomatic. The hypertensive effects may be treated with an alpha-adrenoceptor blocking agent such as phentolamine mesylate, 5 to 10 mg intravenously, repeated as necessary.

IDENTIFICATION

Clear, colourless liquid with a pungent odour.

PRESENTATION

20 ml round, opaque, polyethylene dropper bottle.

STORAGE INSTRUCTIONS

Store at or below 30 °C out of direct sunlight

KEEP ALL MEDICINES OUT OF REACH OF CHILDREN

REFERENCE NUMBER

H1464 (Act 101/1965)

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

Shanur Healthcare (Pty) Ltd

Loch House Unit 003

3A Eton Road, Parktown

Johannesburg, 2193

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