# APPROVED PROFESSIONAL INFORMATION

**SCHEDULING STATUS:**

S2

**PROPRIETARY NAME (AND DOSAGE FORM):**

**SINUEND** (tablets)

**COMPOSITION:**

Each tablet contains:

| | |
|---|---|
| Paracetamol | 200 mg |
| Ephedrine hydrochloride | 6 mg |
| Caffeine anhydrous | 20 mg |
| Chlorpheniramine maleate | 2 mg |

Excipients: Maize starch, lactose, gelatin, Carmoisine Red (CI 14720), Green S (CI 44090), magnesium stearate, talc and sodium starch glycollate.

Contains lactose.

**PHARMACOLOGICAL CLASSIFICATION:**

A 5.8 Preparations for the common cold including nasal decongestants and antihistaminics.

**PHARMACOLOGICAL ACTION:**

SINUEND tablets have analgesic, antipyretic, sympathomimetic and antihistaminic properties.

**INDICATIONS:**

For the symptomatic relief of symptoms associated with colds and influenza such as nasal congestion, and minor aches and pains.

**CONTRAINDICATIONS:**

Hypersensitivity to any of the ingredients.

Severe liver or kidney function impairment.

Cardiovascular disease, kidney disease, hypertension, hyper-thyroidism, hyperexcitability, phaeochromocytoma, closed-angle glaucoma, prostatism, bladder dysfunction.

Patients being treated with monoamine oxidase inhibitors or within 14 days of stopping such treatment.

Epilepsy and all convulsive states.

During an attack of asthma.

**WARNINGS AND SPECIAL PRECAUTIONS:**

Dosages in excess of those recommended may cause severe liver damage.

Patients suffering from liver or kidney disease should take paracetamol under medical supervision.

Consult your doctor if no relief is obtained with the recommended dosage.

**Do not use continuously for longer than ten days without consulting your doctor.**

This medicine may lead to drowsiness and impaired concentration which may be aggravated by the simultaneous intake of alcohol or other central nervous system depressants. Patients should be warned not to drive a motor vehicle, operate dangerous machinery or climb dangerous heights, as impaired decision making could lead to accidents.

Ephedrine hydrochloride should be given with caution to patients with organic heart disease, cardiac decompensation or angina of effort.
Avoid during anaesthesia with cyclopropane, halothane or other halogenated anaesthetics.
Anginal pain may be precipitated in patients with angina pectoris.

Caffeine should be administered with caution to patients with a history of peptic ulceration or hyperacidity.
Prolonged high intake of caffeine may lead to tolerance to some of the pharmacological actions and physical signs of withdrawal if intake is discontinued abruptly.

Elderly patients are most susceptible to the antimuscarinic effects of chlorpheniramine; sedation and hypotension.

**INTERACTIONS:**

An increased risk of arrhythmias may occur if given to patients receiving cardiac glycosides, quinidine, or tricyclic antidepressants.

Chlorpheniramine maleate may enhance the sedative effects of central nervous system depressants including alcohol, barbiturates, hypnotics, opioid analgesics, anxiolytic sedatives and neuroleptics. MAOI's may enhance the antimuscarinic effects of antihistamines.

The effects of antimuscarinic medicines such as atropine and tricyclic antidepressants may also be enhanced.

**PREGNANCY AND LACTATION:**

The safe use of **SINUEND** tablets in pregnancy and lactation has not been established.

**DOSAGE AND DIRECTIONS FOR USE:**

Adults: Two tablets every four hours.

Children: 8 to 12 years: One tablet every four hours.

Not recommended for children under 8 years.

**SIDE EFFECTS:**

Side effects of paracetamol are usually mild, though haematological reactions including thrombocytopenia, leucopenia, pancytopenia, neutropenia and agranulocytosis have been reported.

Pancreatitis, skin rashes and other allergic reactions occur occasionally.

Adverse effects of ephedrine hydrochloride are essentially those of adrenergic and CNS stimulation: fear, anxiety, restlessness, tremor, insomnia, confusion, irritability and psychotic states. Appetite may be reduced, and nausea and vomiting may occur.

Other effects that may occur are difficulty in micturition and urinary retention, dyspnoea, weakness, altered metabolism including disturbances of glucose metabolism, sweating, and hypersalivation. Headache is also common.

Adverse effects of caffeine commonly affect the gastrointestinal tract and CNS.

Chlorpheniramine maleate may cause sedation, varying from slight drowsiness to deep sleep, and including inability to concentrate, lassitude and inco-ordination. Sedative effects may diminish after a few days of treatment. Paradoxical CNS stimulation may occur especially in children, with insomnia, nervousness, euphoria, irritability, tremors and rarely nightmares, hallucinations, and convulsions. In high doses CNS stimulation may be attributed to antimuscarinic activity. Extrapyramidal symptoms may develop. Dry mouth, thickened respiratory secretions and tightness of the chest, blurred vision, urinary difficulty and retention, a reduction in tone and motility of the gastro-intestinal tract resulting in constipation and increased gastric reflux, in high doses, transient bradycardia followed by tachycardia with palpitations and arrhythmias also in high doses CNS stimulation.

Nausea, vomiting, diarrhoea or epigastric pain have occurred.

**KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:**

Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 24 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur.

Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Cardiac arrhythmias have been reported. Symptoms during the first 2 days of acute poisoning do not reflect the potential seriousness of the overdosage. Nausea, vomiting, anorexia and abdominal pain may persist for a week or more. Liver injury may become manifest on the second day, (or later) initially by elevation of serum transaminase and lactic dehydrogenase activity, increased serum bilirubin concentration and prolongation of prothrombin time. The liver damage may progress to encephalopathy, coma and death.
Cerebral oedema and nonspecific myocardial depression have also occurred.

In the event of overdosage consult a doctor or take the patient to the nearest hospital immediately.
Specialised treatment is essential as soon as possible. Any patient who has ingested about 7,5 g of paracetamol in the preceding 4 hours should undergo gastric lavage. Specialised therapy with an antidote such as acetylcysteine or methionine may be necessary. If decided upon, acetylcysteine should be administered IV as soon as possible.

Acetylcysteine:
Acetylcysteine should be administered as soon as possible, preferably within 8 hours of overdosage.

IV: An initial dose of 150 mg/kg in 200 ml glucose injection, given intravenously over 15 minutes, followed by an intravenous infusion of 50 mg/kg in 500 ml of glucose injection over the next 4 hours and then 100 mg/kg

in 1 000 ml over the next 16 hours. The volume of intravenous fluids should be modified for children.

Orally: 140 mg/kg as a 5 % solution initially, followed by a 70mg/kg solution every 4 hours for 17 doses. Acetylcysteine is effective if administered within 8 hours of overdosage.

Symptoms of ephedrine hydrochloride overdosage include paranoid psychosis, delusions and hallucinations. Prolonged administration has no cumulative effect, but tolerance with dependence has been reported.

Symptoms of caffeine overdosage include restlessness, excitement, sensory disturbances, muscle tremor, tinnitus, diuresis, scintillating scotoma, tachycardia and extrasystoles, and convulsions.

In the event of overdosage consult your doctor or take the patient to the nearest hospital immediately.

Specialised treatment is essential as soon as possible.

The latest information regarding the treatment of overdosage can be obtained from the nearest poison centre.

**IDENTIFICATION:**

Red and blue mottled, round, biconvex tablet.

**PRESENTATION:**

White HDPE securitainers containing 20 tablets.

Alu foil / PVC blister packs containing 20 tablets.

**STORAGE INSTRUCTIONS:**

Store at or below 25 ºC. Protect from light and moisture.

**KEEP OUT OF REACH OF CHILDREN**

**REGISTRATION NUMBER:**

29/5.8/0782

**NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE**

**CERTIFICATE OF REGISTRATION:**

Shanur Healthcare (Pty) Ltd

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**DATE OF PUBLICATION OF THE PACKAGE INSERT:**

15 April 1996

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02 February 2015