**SCHEDULING STATUS:** **S1**

**PROPRIETARY NAME:** **ADCO-SINAL® NS**

**(AND DOSAGE FORM)** **(CAPSULE)**

**COMPOSITION:**

Each capsule contains:

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| Phenylephrine hydrochloride | 5 mg |
| Paracetamol | 300 mg |
| Caffeine anhydrous | 25 mg |

Sugar free

List of excipients: starch flowable (pregelatinised), dimethicone, colloidal silicon dioxide

**PHARMACOLOGICAL CLASSIFICATION:**

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

**PHARMACOLOGICAL ACTION:**

**ADCO-SINAL NS** has an analgesic, antipyretic and a nasal decongestant action.

**INDICATIONS**:

For the symptomatic relief of sinus and nasal congestion, pain and fever associated with colds and influenza.

**CONTRAINDICATIONS:**

Hypersensitivity to any of the ingredients.

Severe liver function impairment.

**ADCO-SINAL NS** is contraindicated in persons with coronary disease, hypertension, cardiovascular disease, hyperthyroidism and epilepsy.

It is also contraindicated in patients being treated with monoamine oxidase inhibitors or within 14 days of stopping such treatment.

The safety of **ADCO-SINAL NS** in pregnancy has not yet been established.

Phaeochromocytoma; avoid during cyclopropane, halothane anaesthesia (or any other halogenated anaesthetic).

**WARNINGS:**

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

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

Consult a doctor if no relief is obtained from the recommended dosage.

Do not use continuously for more than 10 days without consulting a doctor.

**DOSAGE AND DIRECTIONS FOR USE:**

**ADCO-SINAL NS** is not recommended for children under 12 years. Do not exceed the recommended dose.

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| *Adults:* | One to two capsules three times a day, with a maximum of four doses in any 24 hours. Do not exceed 8 capsules in any 24 hour period. |
| *Children over 12 years:* | One capsule three times daily. |

**SIDE EFFECTS AND SPECIAL PRECAUTIONS:**

**Paracetamol:**

Skin rashes and other allergic reactions may occur. The rash is usually erythematous or urticarial but sometimes more serious and may be accompanied by fever and mucosal lesions. The use of paracetamol has been associated with the occurrence of neutropenia, pancytopenia and leucopenia.

**Phenylephrine HCl:**

Phenylephrine may cause nausea and vomiting and reduced appetite may occur. It may produce tachycardia, cardiac arrhythmias, anginal pain, palpitations and cardiac arrest, dizziness, fainting and flushing may occur. Agitation, anxiety, reflex bradycardia, confusion, dyspnoea, fear, disturbances of glucose metabolism, insomnia, irritability, miosis, dry mouth, psychotic states, restlessness, sweating, tremor, vasoconstriction which may result in hypertension, cerebral haemorrhage and pulmonary oedema and weakness.

Other effects that may occur are difficulty in micturition and urinary retention. Headache is common.

It should be used with caution in patients who are hypersusceptible to these effects, particularly those with hyperthyroidism. Great care is also needed in patients with cardiovascular disease such as ischaemic heart disease, arrhythmia or tachycardia, occlusive vascular disorders, including arteriosclerosis, hypertension, or aneurisms.

Care is also required when given to patients with diabetes mellitus or closed angle glaucoma. Use carefully in elderly and debilitated patients.

Reversal of the effect of antihypertensive agents may occur. Do not give together with cardiac glycosides, quinidine or tricyclic antidepressant agents.

**Caffeine:**

May cause gastrointestinal irritation and stimulation of the central nervous system. Nausea, vomiting, abdominal pain, gastrointestinal bleeding, insomnia, headache, anxiety, restlessness, vertigo, hypotension and palpitations may occur.

It should be given with caution to patients with peptic ulceration, hyperthyroidism, hypertension, cardiac arrhythmias or other cardiovascular diseases as these conditions may be exacerbated.

It should be given with caution to alcoholics, patients with cor pulmonale, elderly patients, patients with acute febrile conditions, patients with hypoxia, patients with acute pulmonary oedema or any other lung disease or in patients with impaired respiratory function.

## KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

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| In the event of overdosage or suspected overdose and notwithstanding the fact that the person may be asymptomatic, the nearest doctor, hospital or poison control centre must be contacted immediately. |

**Paracetamol:**

Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose 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 non-specific myocardial depression have also occurred.

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.

Prompt treatment is essential. Any patient who has ingested about 7,5 g of paracetamol in the preceding 4 hours should undergo gastric lavage. Specific 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 70 mg/kg solution every 4 hours for 17 doses. Acetylcysteine is effective if administered within 8 hours of overdosage.

**Phenylephrine HCl:**

Kidney failure has been described following acute intoxication.

Overdosage of phenylephrine may cause tachycardia and cardiac arrhythmia, anginal pain, palpitations and cardiac arrest. Restlessness and paranoid psychosis may also occur.

**Caffeine:**

Symptoms of severe overdosage of caffeine may lead to maniacal behaviour, diuresis and repeated vomiting with extreme thirst, tremor, delirium, hyperthermia, tachycardia, tachypnoea, electrolyte disturbances, convulsions and death.

**IDENTIFICATION:**

Size 1 hard gelatin capsule, orange cap and yellow body, filled with a white powder.

**PRESENTATION:**

Cartons containing 20 blister packed capsules or securitainers containing 20 capsules.

**STORAGE INSTRUCTIONS:**

Store at or below 25 $^{o}$C in a dry place. Protect from light.

KEEP OUT OF REACH OF CHILDREN.

**REGISTRATION NUMBER:**

X/5.8/383

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

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**DATE OF PUBLICATION OF THIS PACKAGE INSERT:**

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