Professional Information

SCHEDULING STATUS

S2

PROPRIETARY NAME AND DOSAGE FORM

DEMAZIN FLU

QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients: 30 mg Pseudoephedrine Hydrochloride, 20 mg Dextromethorphan Hydrobromide, 300 mg Paracetamol, 125 mg Ascorbic acid.

Inactive ingredients: caramel powder, fumaric acid, lemon flavour, mannitol, povidone, sodium bicarbonate, sodium chloride.

Contains sugar: mannitol 65 mg, sorbitol 2 g. Contains sweetener: aspartame: 75 mg.

PHARMACOLOGICAL CLASSIFICATION

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

PHARMACOLOGICAL ACTION

DEMAZIN FLU has antitussive, analgesic, antipyretic and sympathomimetic effects.

INDICATIONS

Relief symptoms such as cough, nasal congestion, minor fever, minor pain associated with colds and influenza.

CONTRAINDICATIONS

Patients with known sensitivity to the active ingredients or excipients. Severe or uncontrolled hypertension, severe coronary heart disease, severe impairment of hepatic function or severe acute or chronic renal disease or failure. Safety in pregnancy and lactation has not been established. [SEE PREGNANCY AND LACTATION]

WARNING AND SPECIAL PRECAUTIONS

Dosage in excess of those recommended may cause severe liver damage. Do not use continuously for longer than 10 days without consulting your doctor. Consult a doctor if no relief is obtained with the recommended dosage.

Do not use this product if you are presently taking monoamine oxidase inhibitors or other medicines for depression, psychiatric or emotional conditions or hypertension.

Pseudoephedrine is associated with risks of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS). These are rare conditions that can involve reduced blood supply to the brain, potentially causing serious, life-threatening complications. Discontinue treatment immediately if any symptoms of PRES or RCVS, such as a sudden severe headache, feeling sick, vomiting, confusion, seizures and visual disturbances occur.

SPECIAL PRECAUTIONS

Pseudoephedrine hydrochloride should be given with caution to patients hyper-susceptible to its effect, especially those with hyperthyroidism, diabetes mellitus or closed angle glaucoma. Use with caution in patients undergoing anaesthesia with cyclopropane, halothane or other halogenated anaesthetics as they may include ventricular fibrillation. Ascorbic acid should be given with care to patients with hyperoxaluria.

INTERACTIONS

Interaction with monoamine oxidase inhibitors cannot be excluded, - pseudoephedrine should not be given to patients receiving such treatment or within 14 days of its termination.

Reversal of antihypertensive therapy may occur if pseudoephedrine is given concomitantly.

Pseudoephedrine could enhance the central stimulant effects of other sympatho-mimetics.

An increased risk of arrythmias may occur if pseudoephedrine is given to patients receiving cardiac glycosides, quinine or tricyclic antidepressants.

PREGNANCY AND LACTATION

Safety in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE

Do not remove from tube until immediately before use.

Adults and children over 12 years of age: Dissolve 2 effervescent tablets in a glass of very hot, but not boiling water; drink when still very hot. Repeat with 2 effervescent tablets every 4 hours (maximum 6 tablets in 24 hours).

DEMAZIN FLU is not suitable for children under 12 years of age.

SIDE EFFECTS

Table 1: The following side-effects have been reported and the frequencies are unknown

Blood and the lymphatic system disorders	Haemotology reactions including Neutropaenia, pancytopaenia, and leucopaenia
Immune system disorders	Allergic reaction
Metabolism and nutrition disorders	Altered metabolism (including glucose metabolism)
Psychiatric disorders	Anxiety, restlessness, insomnia, confusion, psychotic states
Nervous system disorders	Headache, fainting, dizziness, tremor, weakness
Cardiac disorders	Vasoconstriction hypertension, tachycardia, cardiac arrythmias, anginal pain, palpitations and cardiac arrest.
Vascular disorders	Hypotension with dizziness, flushing
Respiratory, thoracic and mediastinal disorders	Dyspnoea
Gastrointestinal disorders	Gastro-intestinal disturbances, reduction of appetite, nausea, vomiting, diarrhoea, renal calcium oxalate calculi.
Skin and subcutaneous tissue disorders	Skin rash (erythematous or urticarial) with mucosal lesions, sweating
Renal and urinary disorders	Micturition, urinary retention.
General disorders and administrative site conditions	Fear, irritability, hypersalivation.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Tolerance may be induced with prolonged use of large doses.

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 metabolism and metabolic acidosis may occur.

Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Cardiac arrythmias have been reported.

Symptoms during the first 2 days of poisoning do not reflect the potential seriousness of the overdosage. Nausea, vomiting, anorexia, abdominal pain may persist for a week or more. Liver injury may manifest on he second day, (or later) initially be 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 your doctor or take the patient to the nearest hospital immediately.

Specialized treatment is essential as soon as possible.

Prompt treatment is essential. Any patient who has ingested about 7,5 g of paracetamol in the proceeding 4 hours should undergo gastric lavage. Specific therapy with an antidote such as acetylcysteine or methionine may be necessary. I decided upon, acetylcysteine should be administered IV as soon as possible.

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

IV: An initial dose of 150 m/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, then 100 mg/kg in 1000 ml over the next 16 hours. The volume of intravenous fluid 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.

Excitation, confusion and respiratory depression may occur after overdosage of dextromethorphan.

Symptoms from pseudoephedrine overdose consist most often of mild anxiety, tachycardia and/or mild hypertension.

Large doses of ascorbic acid may cause diarrhoea and other gastro-intestinal disturbances and are associated with the formation of renal calcium oxalate calculi.

IDENTIFICATION

Biplane orange-grey effervescent tablets.

PRESENTATION

12 or 24 Effervescent tablets packed in tubes.

STORAGE INSTRUCTIONS

Store in a dry place at or below 25 °C.

Do not remove tablet from tube until immediately prior use.

Keep out of the reach of children.

REGISTRATION NUMBER

Y/5.8/308

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

iNova Pharmaceuticals (Pty) Ltd

15E Riley Road

Bedfordview

2007

DATE OF PUBLICATION OF THIS PACKAGE INSERT

Date on the registration certificate of the medicine: 12 May 2005

Date of publication of this package insert: 25 March 1994