1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S2

PROPRIETARY NAME AND DOSAGE FORM

FLUTEX COLD AND FLU CAPSULES WITH VITAMIN C

COMPOSITION

Each capsule of FLUTEX COLD AND FLU CAPSULES WITH VITAMIN C contains 2 mg of chlorphenamine maleate, 2 mg of phenylephrine hydrochloride, 100 mg of paracetamol, 75 mg of salicylamide, 50 mg of ascorbic acid and 30 mg of caffeine anhydrous.

Excipients:

Erythrosine (C.I. 45430), gelatin, sodium benzoate, starch maize, sunset yellow (C.I. 15985), talc purified, titanium dioxide (C.I. 77891)

Preservative:

Sodium benzoate 0,011 % *m/m*

Sugar free

CATEGORY AND CLASS

A 5.8 Preparations for the common cold, including nasal decongestants

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

FLUTEX COLD AND FLU CAPSULES WITH VITAMIN C have analgesic, antihistaminic and decongestant properties.

INDICATIONS

FLUTEX COLD AND FLU CAPSULES WITH VITAMIN C are indicated for the relief of symptoms associated with colds and influenza such as nasal congestion, headache, minor aches and pains.

CONTRAINDICATIONS

FLUTEX COLD AND FLU CAPSULES WITH VITAMIN C are contraindicated in:

- Hypertension.
- Cardiovascular disease.
- Hyperthyroidism.
- Hypersensitivity to any of the ingredients.
- Pregnancy.
- Persons being treated with monoamine oxidase inhibitors or within 14 days of stopping such treatment.
- Severe liver function impairment.
- Children under six years of age.

WARNINGS AND SPECIAL PRECAUTIONS

Dosage in excess of those recommended may cause severe liver damage. Do not use continuously for more than 10 days without consulting your doctor.

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

FLUTEX COLD AND FLU CAPSULES WITH VITAMIN C may lead to drowsiness and

impaired concentration, which may be aggravated by the simultaneous intake of alcohol or other central nervous system depressant medicines.

Paracetamol

Paracetamol, as contained in FLUTEX COLD AND FLU CAPSULES WITH VITAMIN C, should be given with care to patients taking other medicines that affect the liver.

Caffeine

Caffeine, as contained in FLUTEX COLD AND FLU CAPSULES WITH VITAMIN C, should be given with care to patients with a history of peptic ulceration.

Salicylamide

Salicylamide, as contained in FLUTEX COLD AND FLU CAPSULES WITH VITAMIN C, should not be administered to patients with haemophilia or other haemorrhagic disorders.

Aspirin has been implicated in Reye's Syndrome, a rare but serious illness, in children and teenagers with chickenpox and influenza. Since salicylamide is a compound related to aspirin, a doctor should be consulted before this product is used in such patients.

Ascorbic acid

Use with care in patients with hyperoxaluria.

Phenylephrine hydrochloride

Use with caution in patients with hyperthyroidism, cardiovascular disease, diabetes mellitus or closed-angle glaucoma.

Effects on ability to drive and use machines

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.

Chlorphenamine may produce sedation.

INTERACTIONS

Chlorphenamine maleate

Care should be observed when tricyclic antidepressants, guanethidine, reserpine, methyldopa or atropine are taken concomitantly.

Other central nervous system depressants, such as barbiturates, hypnotics, narcotic analgesics, sedatives and tranquillisers, if taken concomitantly, will enhance sedation.

Phenylephrine hydrochloride

An increased risk of dysrhythmias may also occur if phenylephrine, as contained in FLUTEX COLD AND FLU CAPSULES WITH VITAMIN C, is given to patients receiving cardiac glycosides, quinidine or tricyclic antidepressants.

HUMAN REPRODUCTION

Contraindicated in pregnancy (see CONTRAINDICATIONS).

DOSAGE AND DIRECTIONS FOR USE

Adults:

Take one to two capsules 3 times a day after meals.

Children (6 to 12 years):

Take one capsule 3 times a day after meals.

Not recommended for children under the age of 6 years (see CONTRAINDICATIONS).

Do not exceed the stated dose.

SIDE EFFECTS

Paracetamol

Blood and the lymphatic system disorders

Thrombocytopenia, leucopenia, pancytopenia and agranulocytosis may occur.

Immune system disorders

Skin rashes and other hypersensitivity reactions may occur.

Caffeine anhydrous

Gastrointestinal disorders

Gastrointestinal irritation, nausea, vomiting, abdominal pain, diarrhoea, gastrointestinal bleeding.

Psychiatric disorders

Insomnia, anxiety, restlessness.

Nervous system disorders

Stimulation of the central nervous system, headache, dizziness, tremor.

Cardiac disorders

Palpitations.

Vascular disorders

Hypotension.

Salicylamide

Immune system disorders

Sensitivity to salicylamide may produce skin rashes, angioedema, rhinitis, severe paroxysmal bronchospasm and dyspnoea.

Gastrointestinal disorders

Gastrointestinal disturbances such as nausea, dyspepsia and vomiting. Irritation of the gastric mucosa with erosion, ulceration, haematemesis and melaena may occur.

Hepatobiliary disorders

Salicylamide may cause hepatotoxicity, especially in patients with juvenile arthritis or other connective tissue disorders.

Ascorbic acid

Gastrointestinal disorders

Large doses causes diarrhoea and other gastrointestinal disturbances.

Chlorphenamine maleate

Metabolism and nutrition disorders

Anorexia.

Psychiatric disorders

Irritability, nightmares.

Nervous system disorders

Sedation, dizziness, incoordination, tremors, headache.

Eye disorders

Blurred vision.

Ear and labyrinth disorders

Tinnitus.

Gastrointestinal disorders

Gastrointestinal disturbances, dryness of mouth.

Renal and urinary disorders

Difficulty in micturition.

General disorders and administrative site conditions

Tightness of chest, lassitude.

Phenylephrine hydrochloride

Metabolism and nutrition disorders

May cause reduced appetite.

Psychiatric disorders

May cause anxiety, fear, confusion, psychotic states, restlessness and insomnia.

Nervous system disorders

May cause tremors, giddiness, headache.

Cardiac disorders

Hypertension and ventricular dysrhythmias may occur. Phenylephrine may cause tachycardia, palpitations.

Gastrointestinal disorders

May cause nausea, vomiting, hypersalivation.

Renal and urinary disorders

May cause difficulty in micturition, urinary retention.

General disorders and administrative site conditions

May cause sweating.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 24 hours 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 dysrhythmias 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 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.

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, 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 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.

Symptoms of caffeine overdosage include tremor, delirium, tachycardia, cardiac dysrhythmia, convulsions, and death may occur.

Symptoms of salicylamide overdosage include hyperventilation, fever, restlessness, ketosis, and respiratory alkalosis and metabolic acidosis. Depression of the central nervous system may lead to coma; cardiovascular collapse and respiratory failure can occur.

In children drowsiness and metabolic acidosis commonly occur, hypoglycaemia may be severe.

In acute salicylamide overdosage, the stomach should be emptied by lavage. Fluid and electrolyte management is the mainstay of treatment with the immediate aim being correction of acidosis, hyperpyrexia, hypokalaemia and dehydration.

Symptoms of chlorphenamine overdosage include ataxia, excitement, tremors, psychoses, hallucinations, and convulsions; hyperpyrexia may also occur. Deepening coma and cardiorespiratory collapse may follow.

IDENTIFICATION

A size 1 hard gelatin capsule with an opaque orange cap and an opaque white body, containing a homogenous granular white to straw coloured powder, imprinted in black ink with “FLUTEX” on cap and body.

PRESENTATION

20 capsules are packed in a white cylindrical polypropylene container together with a silica gel sachet and sealed with a white liner low density polyethylene cap.

20 capsules are packed in a white high density polyethylene bottle together with a silica gel sachet and sealed with a white opaque polypropylene cap with continuous threading.
Not all packs are necessarily marketed.

STORAGE INSTRUCTIONS

Store at or below 25 °C, in airtight containers and protect from light and moisture.
Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

G1221 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF THE APPLICANT

PHARMACARE LIMITED

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DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

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