Scheduling status:
S2

Proprietary Name and Dosage Form:

FAMUCAPS CAPSULES

Composition:
Each capsule contains:

Phenylephrine hydrochloride	5 mg
Chlorpheniramine maleate	2 mg
Paracetamol	300 mg

Pharmacological Classification:
A/5.8/ Preparations for the common cold including nasal decongestants.

Pharmacological Action:
This preparation has antihistaminic, decongestant, analgesic and antipyretic properties.

Indications:
For the symptomatic relief of sinusitis, rhinitis and allergic conditions of the upper respiratory tract, hay fever and influenza.

Contra-indications:
This product should not be used in the following instances:
- Hypersensitivity to any of the ingredients.
- Pregnancy and lactation
- Heart disease, epilepsy, hypertension or hyperthyroidism.
- Patients on monoamine oxidase inhibitors or within 10 days of stopping such treatment.
- Not recommended for use in children under six years.
- Patients suffering from hepatitis or alcoholism or recovering from any form of liver disease, should not take products containing paracetamol.

Warnings:
This medicine may lead to drowsiness and impaired concentration which may be aggravated by the simultaneous intake of alcohol or other central nervous system depressant agents.
Patients should be warned not to drive a motor vehicle, handle heavy machinery or to climb dangerous heights, because lowering of concentration may lead to accidents.
Dosages in excess of the recommended dose can cause severe liver damage.
Do not use continuously for more than 10 days without consulting your doctor.

Interactions:
All sedatives, including alcohol, will potentiate depressant effects on the central nervous system if taken with antihistamines.
Medications tending to cause extrapyramidal reactions and those with anticholinergic effects may be potentiated. These include atropine, tricyclic antidepressants, maprotiline, reserpine, guanethidine and monoamine oxidase inhibitors. Antihistamines may suppress positive skin test results and should be stopped several days before the test.

Pregnancy and Lactation:
Pregnant and lactating women should not use this product without consulting their doctor.

Dosage and directions for use:

Adults:	2 capsules 3 times a day.
Children: 6-12 years:	1 capsule 3 times a day.

Not recommended for children under the age of 6 years.

Side-effects and special precautions:

The following side-effects were reported:

Phenylephrine hydrochloride:
Headache, fear, anxiety, restlessness, tremor, flushing, dyspnoea, weakness, insomnia, confusion, irritability and psychotic states. Appetite may be reduced and nausea and vomiting may occur. Hypertension, palpitations, tachycardia, reflex bradycardia, anginal pain in angina pectoris and cardiac arrest may occur. Difficulty in micturition and urinary retention, cerebral haemorrhage, pulmonary oedema, altered metabolism, including blood sugar, have been reported.

Chlorpheniramine maleate:
Central nervous system: sedation, drowsiness, nervousness, fatigue, dizziness, tremors, incoordination, insomnia, tinnitus, confusion, hallucinations, convulsions, headache.
Extrapyramidal effects with muscle spasm and dystonia.
Cerebral stimulation, particularly in children, allergy and anaphylaxis may occasionally occur.
Anticholinergic effects with ataxia, flushing, blurred vision, dryness of the mouth and nose, thickening of mucous, urinary retention or frequency, dysuria, reduction in tone and motility of the gastro-intestinal tract, resulting in constipation and increased gastric reflux may occur. Elderly patients are especially subject to dizziness, sedation, confusion, hypotension and to anticholinergic effects such as dry mouth and urinary retention.
Gastro-intestinal disturbances such as nausea, vomiting, diarrhoea or epigastric pain have occurred with antihistamines.
Hypotension, tachycardia, blood dyscrasias including agranulocysotis, leukopenia, haemolytic anaemia and thrombocytopenia have been reported. Photosensitivity and skin rash, allergic dermatitis, drug fever.

Paracetamol:
Dosages in excess of those recommended may cause severe liver damage. Pancreatitis, skin rashes and other allergic reactions may occur. The rash is usually erythematous or urticarial but sometimes more serious and accompanied by fever and mucosal lesions. Agranulocytosis, thrombocytopenia, leucopoenia, pancytopenia. Neutropenia, anaemia, dermatitis, hepatitis, renal colic, renal failure and sterile pyuria, have occurred.

Precautions:
Consult your doctor if:
- no relief is obtained with the recommended dosage;
- fever persists for more than 3 days
- usage is required for more than 10 days

Care has to be taken in patients with:
renal disease, severe cardiovascular disorders, liver disease, hyperthyroidism, diabetes mellitus, glaucoma, pyloroduodenal obstruction, prostatic hypertrophy, emphysema, chronic bronchitis, porphyria, paradoxical hyper excitability, epilepsy, nervousness and insomnia.

Known Symptoms of over dose and particulars of its treatment:

Symptoms:

Symptoms of over dose with phenylephrine - see **side-effects**.

Chlorpheniramine over dose may result in drowsiness, or paradoxical excitement, hallucinations, ataxia, incoordination, athetosis, convulsions in susceptible persons and hypotension. Fixed, dilated pupils with a flushed face, sinus tachycardia, dyspnoea, and urinary retention, dry mouth and fever. Terminally, deepening coma, cardiorespiratory collapse. Children and the elderly are more likely to exhibit anticholinergic and central nervous system stimulant effects. The elderly are prone to hypotension.

Symptoms of paracetamol overdose in the first 24 hours are pallor, nausea, vomiting, anorexia, and abdominal pain. Liver damage may become apparent 12 - 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 arrhythmia has been reported. Symptoms of the first 2 days of acute poisoning do not reflect the potential seriousness of the over dose. Nausea, vomiting, anorexia and abdominal pain may persist for a week or more. Liver damage may become apparent on the second day (or later) initially by elevation of serum transaminase and lactic dehydrogenase activity, increased serum billirubin 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.

Treatment:
An over dose may potentially be fatal, particularly in children and elderly patients. In the event of an over dose or suspected over dose, prompt medical treatment is critical, even if no obvious signs or symptoms are present. The nearest doctor, a hospital or a poisons control centre must be contacted immediately. All patients with significant over dose should be monitored for at least 90 hours. Symptoms of liver damage, which may be fatal, may only appear after a few days. A plasma paracetamol level should be determined four hours after ingestion in all cases of suspected over dose. Levels done before 4 hours, unless high may be misleading. Patients at risk of liver damage and hence requiring continued treatment with N-acetylcysteine, can be identified according to their plasma paracetamol level. Any patient who has ingested about 7,5 g of paracetamol in the preceding 4 hours should undergo gastric lavage (emesis may be adequate tor children) and a single dose of 50 g activated charcoal given via the lavage tube. Specific therapy with an antidote such as acetylcysteine may be required.

ACETYLCYSTEINE:
Acetylcysteine should be administered as soon as possible.

ORALLY (not the treatment of choice): 140 mg/kg as a 5% solution initially, within 8 hours of over dose, followed by a 70 mg/kg solution every 4 hours for 17 doses.

INTRAVENOUSLY: An initial dose of 150 mg/kg acetylcysteine in 200 mℓ glucose 5% infusion is given intravenously over 15 minutes, followed by 50 mg/kg in 500 mℓ glucose 5% infusion given intravenously over the next 4 hours and then 100 mg/kg in a 1000 mℓ glucose 5% infusion administered intravenously over the next 16 hours. The volume of intravenous fluids should be modified for children.

Identification:
Multi-coloured size "0" gelatine capsule (brown and white).

Presentation:
Polyethylene containers containing 20 or 1 000 capsules.

Storage Instructions:
Keep in a cool, dry place below 25°C. KEEP OUT OF REACH OF CHILDREN.

Reference Number:
G1235 (Wet/Act 101/1965)

Name and business address of the holder of the certificate of registration:
Brunel Laboratoria (Pty) Ltd
1 Van Tonder Street
Sunderland Ridge
Centurion

DATE OF PUBLICATION OF THIS PACKAGE INSERT: