1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S2

PROPRIETARY NAME AND DOSAGE FORM

HISTACON CAPSULES

COMPOSITION

Each capsule of HISTACON CAPSULES contains:

Chlorphenamine maleate	2 mg
Phenylephrine hydrochloride	5 mg
Paracetamol	200 mg
Caffeine	30 mg

Excipients:

Brilliant blue (C.I. 42090), erythrosine (C.I. 45730), gelatin, methyl paraben, propyl paraben, purified talc, quinolone yellow (C.I. 47005), sodium lauryl sulphate, titanium dioxide (C.I. 77891)

Preservatives:

Methyl paraben 0,128 *% m/m*
Propyl paraben 0,032 *% m/m*

Sugar free

CATEGORY AND CLASS

A 5.8 Preparations for the common cold including nasal decongestants

PHARMACOLOGICAL ACTION

HISTACON CAPSULES is an analgesic and antipyretic preparation with antihistaminic and decongestant action.

INDICATIONS

For the relief of colds, influenza, hayfever, sinusitis, acute rhinitis, post nasal drip and nasal allergies.

CONTRAINDICATIONS

Hypersensitivity to any of the ingredients.

Hyperthyroidism, aneurysm, hypertension, arteriosclerosis and cardiovascular disorders such as ventricular tachycardia, myocardial disease or bradycardia. It is unadvisable to use sympathomimetic amines or medicines containing them in late pregnancy, or for patients being treated with monoamine oxidase inhibitors or within 14 days of stopping such treatment. Do not use concomitantly with tricyclic antidepressants. Severe liver function impairment.

WARNINGS AND SPECIAL PRECAUTIONS

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

This medicine may lead to drowsiness and impaired concentration which may be aggravated by simultaneous intake of alcohol or other central nervous system depressant agents. Patients

should be warned against taking charge of vehicle or machinery or performing potentially hazardous tasks where loss of concentration may lead to accidents.

Paracetamol

Paracetamol should be given with care to patients with impaired kidney or liver function and patients taking other medicine that affect the liver. Do not exceed the recommended dosage.

Phenylephrine hydrochloride

It should be used with caution in patients with hyperthyroidism. Great care is needed in patients with cardiovascular disease such as ischaemic heart disease, arrhythmia or tachycardia, occlusive vascular disease, including arteriosclerosis, hypertension or aneurysms. Anginal pain may be precipitated in patients with angina pectoris. Care should be given to patients with diabetes mellitus or closed-angle glaucoma.

Chlorphenamine maleate

Because of the antimuscarinic properties it should be used with care in conditions such as narrow angle glaucoma, urinary retention, and prostatic hypertrophy.

Caffeine

It should be given with caution to patients with peptic ulceration, hypertension, hyperthyroidism, cardiac arrhythmias or other cardiovascular disease as these conditions may be exacerbated. It should be given with caution to patients with congestive heart failure, hepatic dysfunction or chronic alcoholism, acute febrile illness, severe hypoxia, cor pulmonale, acute pulmonary oedema or other chronic lung disease and the elderly since in all the circumstances the clearance may be decreased, resulting in increases in the serum concentrations and serum half-life.

Effects on ability to drive and use machines

Patients should be warned against taking charge of vehicle or machinery or performing potentially hazardous tasks where loss of concentration may lead to accidents.

INTERACTIONS

Paracetamol

Gastrointestinal absorption of paracetamol may be delayed by some drugs such as anticholinergic agents or opioid analgesics which decrease gastric emptying. The likelihood of toxicity may be increased by the concomitant use of enzyme-inducing agents such as alcohol or anti-epileptic drugs. Repeated doses of paracetamol increase somewhat the anticoagulant response to coumarin and paracetamol may also increase the chloramphenicol concentrations.

Phenylephrine hydrochloride

Sympathomimetics should be avoided or used with caution in patients undergoing anaesthesia with cyclopropane, halothane or other halogenated anaesthetics as they may induce ventricular fibrillation. An increased risk of arrhythmias may also occur if sympathomimetic agents are given to patients receiving cardiac glycosides, quinidine or tricyclic antidepressants. Many sympathomimetics interact with monoamine oxidase inhibitors and should not be given to patients receiving such treatment or within 14 days of its termination. Reversal of the action of many antihypertensive agents occurs and therefore special care is advisable in patients receiving antihypertensive therapy.

Chlorphenamine maleate

MAOI's may enhance the antimuscarinic effects of antihistamines and antihistamines have an

additive antimuscarinic action with other antimuscarinic agents such as atropine and tricyclic antidepressants.

Antihistamines may enhance the sedative effects of central nervous system depressants including alcohol, barbiturates, hypnotics, narcotic analgesic sedatives and tranquillisers. It could mask the warning signs of damage caused by ototoxic drugs such as aminoglycoside antibiotics. Antihistamines may suppress positive skin test results and should be stopped several days before the test.

Caffeine

Caffeine reduces plasma flow in the liver and may therefore prolong the half-life and increase steady-state concentrations of hepatically eliminated drugs.

HUMAN REPRODUCTION

HISTACON CAPSULES should not be used during pregnancy and lactation.

DOSAGE AND DIRECTIONS FOR USE

Adults: One to two capsules four times per day.

SIDE-EFFECTS

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 hydrochloride

Central effects: fear, anxiety, restlessness, tremor, insomnia, confusion, irritability, weakness and psychotic states. Appetite may be reduced and nausea and vomiting may occur.

Effects on the cardiovascular system:

1) Stimulation of the alpha-adrenergic receptors causes vasoconstriction, sometimes sufficiently severe to cause gangrene when infiltrated into the digitis, with resultant hypertension which may produce cerebral haemorrhage and pulmonary oedema. There may also be reflex bradycardia.
2) Stimulation of the β_1-adrenergic receptors of the heart may produce tachycardia and cardiac arrhythmias, anginal pain, palpitations and cardiac arrest, hypotension with dizziness and fainting and flushing may occur.

Other effects: Difficulty in micturition and urinary retention, dyspnoea, altered metabolism, including disturbances of glucose metabolism, sweating and hypersalivation. Headache is also common.

Chlorphenamine maleate

The most common effect is sedation, including lassitude, dizziness and inco-ordination. Sedative effects may diminish after a few days.

Other side effects include gastrointestinal disturbances such as nausea, vomiting, diarrhoea or constipation, anorexia or increased appetite and epigastric pain. Chlorphenamine maleate may produce antimuscarinic effects including blurred vision, difficulty in micturition, dysuria, dryness of

mouth and tightness of the chest. Other central effects include hypotension, muscular weakness, tinnitus, euphoria and occasionally headache. Paradoxical CNS stimulation may occur especially in children, with insomnia, nervousness, tachycardia, tremors and convulsions. Epileptiform seizures may be precipitated in patients with focal lesions of the cerebral cortex. Blood disorders, including agranulocytosis, leucopenia and haemolytic anaemia have been reported.

Caffeine

Side effects commonly encountered are gastrointestinal irritation and stimulation of the central nervous system. It may cause nausea, vomiting, abdominal pain, gastrointestinal bleeding, insomnia, headache, anxiety, restlessness, vertigo, tremor, sleeplessness and palpitations.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Paracetamol

Symptoms

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 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 manifest on the second day, (or later) initially by elevated 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.

Treatment

Specialised treatment is essential as soon as possible. Prompt treatment is essential. Any patient who has ingested 7,5 gram or more 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.

See SIDE EFFECTS above.

Further treatment is symptomatic and supportive.

IDENTIFICATION

Opaque gelatin capsule size no. 1 consisting of a blue cap and white body, containing fine white powdery granulate.

PRESENTATION

1 000 capsules are packed in a white high density polyethylene jar with white flat cap with low density polyethylene liner together with a white foam insert.

STORAGE INSTRUCTIONS

Store at or below 25 °C in a dry place and keep well closed.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

C839 (Act 101/1965)

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

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

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

Date of registration: Old medicine

Date of the most recent amendment to the professional information as approved by the Authority:

01 September 1970

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