SCHEDULING STATUS: S2
PROPRIETARY NAME (and dosage form):

PAINCODEIN TABLETS

COMPOSITION:

Each tablet contains:

Paracetamol	500 mg
Codeine Phosphate	8 mg

Contains Sucrose.

Preservatives:

Nipastat	0.07 % m/m
Benzoic acid	0.06 % m/m

PHARMACOLOGICAL CLASSIFICATION:

Category A 2.8 Analgesic Combinations.

PHARMACOLOGICAL ACTION:

PAINCODEIN has analgesic and antipyretic action.

INDICATIONS:

PAINCODEIN TABLETS are indicated for the symptomatic relief of mild to moderate pain and fever.

CONTRA-INDICATIONS:

Sensitivity to any of the ingredients.

Not for use in children under six years of age.

Severe liver function impairment.

Codeine is contra-indicated in respiratory depression, especially in the presence of cyanosis and excessive bronchial secretion during an attack of bronchial asthma or in heart failure secondary to Lung disease and after operations on the biliary tract; in the presence of acute alcoholism, head injuries and conditions in which intracranial pressure is raised.

WARNINGS:

The use of 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 against taking charge of vehicles or performing potentially hazardous tasks, where loss of concentration may lead to accidents.

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

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

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

Consult your doctor if no relief is obtained with the recommended dosage.

DOSAGE AND DIRECTIONS FOR USE:

Adults: One or two tablets every four to six hours.

Children over 12 years: One tablet every four to six hours.

Children 6 to 12 years: Half to one tablet every six hours.

Do not take more than eight tablets daily.

Do not use continuously for longer than ten (10) days without consulting your doctor.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Paracetamol:

Sensitivity reactions resulting in reversible rash or blood disorders including neutropenia, pancytopenia and leucopenia may occur. The rash is usually erythematous or urticarial but sometimes more serious and may be accompanied by fever and mucosal lesions.

Codeine:

Codeine may cause nausea, vomiting, constipation, drowsiness, confusion, dry mouth, sweating, facial flushing, vertigo, bradycardia, palpitations, orthostatic hypotension, hypothermia, restlessness, changes of mood and miosis. Micturition may be difficult and there may be ureteric or biliary spasm. Raised intracranial pressure may occur. Reactions such as urticaria and pruritus may occur.

Codeine should be given with caution to patients with hypothyroidism, adrenocortical insufficiency myasthenia gravis, impaired liver or kidney function, prostatic hypertrophy or shock. It should be used with caution in patients with inflammatory or obstructive bowel disorders. The dosage should be reduced in elderly and debilitated patients.

The depressant effects of codeine are enhanced by depressants of the central nervous system such as alcohol, anaesthetics, hypnotics and sedatives, phenothiazines, and tricyclic antidepressants.

The prolonged use of high doses of codeine has produced dependence of the morphine type.

Codeine should be given with extreme caution in patients taking monoamine oxidase inhibitors or within 14 days of stopping such treatment.

The administration of codeine during labour may cause respiratory depression in the new born infant.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

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

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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 nonspecific 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.

Prompt treatment is essential. Any patient who has ingested about 7.5 g of paracetamol in the preceeding 4 hours should undergo gastic 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 50mg/kg in 500ml of glucose injection over the next 4 hours, and then 100 mg/kg in 1000 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 administrated within 8 hours of overdosage.

Codeine:

Symptoms include restlessness, excitement, respiratory depression and hypotension with circulatory failure and coma. In children convulsions may occur. The specific antagonist, naloxone hydrochloride is used to counteract the severe respiratory depression.

In the event of overdosage, consult a doctor or take the patient to the nearest hospital immediately.

Further treatment is supportive and symptomatic.

IDENTIFICATION:

Flat green tablet, scored on the one side and plain on the other side.

PRESENTATION:

Blister packs containing 2 x 10 and 10 x 10 tablets and plastic bottles containing 100, 500 and 1000 tablets.

STORAGE INSTRUCTIONS:

Store at or below 25 ^{o}C and protect from intense light in a well closed container. Protect from moisture. Exposure to air should be minimum.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

Y/2.8/306

NAME AND BUSINESS ADDRESS OF APPLICANT:

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1683

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