PROPRIETARY NAME: Cipyne® Capsules

COMPOSITION:
Each capsule contains:

Codeine Phosphate	10mg
Ibuprofen	200mg
Paracetamol	250mg

CATEGORY OF DISTRIBUTION
Pharmacy only

PHARMACOLOGICAL CLASSIFICATION:
N02AJ09: Codeine and other non-opioid analgesics

PHARMACOLOGICAL ACTION:
CIPYNE® CAPSULES have an analgesic, anti-inflammatory and antipyretic action.

INDICATIONS:
CIPYNE® CAPSULES are indicated for the relief of mild to moderate pain of inflammatory origin with or without fever.

CONTRAINDICATIONS:
Impaired hepatic and renal function, peptic ulceration, cardiovascular disease and hypersensitivity to any of the active ingredients.
Contraindicated in respiratory depression, especially in the presence of cyanosis and excessive bronchial secretion, after operations of the biliary tract, acute alcoholism, head injuries and conditions in which intracranial pressure is raised. It should not be given during an attack of bronchial asthma or in heart failure secondary to lung disease.
Contraindicated in patients taking monoamine oxidase inhibitors or within fourteen days of stopping such treatment.
Caution is advised in those patients who are receiving coumarin anticoagulants.
Patients who are sensitive to aspirin should not be given CIPYNE® CAPSULES.

WARNINGS:
The safety of continuous administration of CIPYNE® CAPSULES has not been established for a period greater than four weeks.
Codeine: Exceeding the prescribed dose, together with prolonged and continuous use of this medication may lead to dependency and addiction.
Paracetamol: Dosages in excess of those recommended may cause severe liver damage.

PREGNANCY AND LACTATION:
CIPYNE® CAPSULES are not recommended for use by pregnant or breast feeding women.
Regular use of NSAID's during the third trimester of pregnancy may result in premature closure of the foetal *ductus arteriosus in utero* and possibly in persistent pulmonary hypertension of the newborn. The onset of labor may be delayed and its duration increased.

DOSAGE AND DIRECTIONS FOR USE:
Not recommended for children under twelve years of age.
Adults: One to two capsules four hourly and not more than twelve capsules per twenty four hours. Consult your doctor if no relief is obtained with the recommended dosage.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:
In view of the product's inherent potential to cause fluid retention, heart failure may be precipitated in some compromised patients.
Ibuprofen: Peptic ulceration and gastrointestinal bleeding have been reported. Other side effects include dizziness, dyspepsia, nausea, nervousness, skin rash, pruritus, tinnitus, oedema, depression, drowsiness, insomnia, blurred vision and other ocular reactions.
Hypersensitivity reactions, abnormalities of liver function tests, impairment of renal function, agranulocytosis and thrombocytopenia have occasionally been reported. Acute reversible renal failure has been reported. Ibuprofen should be used with care in patients with impaired renal function.

Paracetamol: Sensitivity reactions resulting in reversible skin rash or blood disorders may occur. Haemotological reactions have been reported.

Codeine Phosphate: Codeine phosphate may cause nausea, vomiting, constipation, drowsiness, confusion, dry mouth, sweating, facial flushing, vertigo, bradycardia, palpitations, orthostatic hypotension, hypothermia, restlessness, changes of mood and misosis. Micturation may be difficult and there may be ureteric or billiary spasm. Raised intracranial pressure may occur. Reactions such as urticaria and pruritus may occur. Codeine phosphate should be given with caution to 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, and phenothiazines.
The prolonged use of high doses of codeine has produced dependence of the morphine type.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES
Undesirable effects such as dizziness, drowsiness, fatigue and visual disturbances are possible since the medicine contains an NSAID. If affected patients should not drive or operate machinery.

KNOWN SYMPTOMPS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Paracetamol:
Symptoms of paracetamol overdosage in the first 24hours 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 become manifest on the second day or later, initially by elevation of serum transaminase and lactic dehydrogenase acticity, 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. Prompt treatment is essential. Any patient who has ingested about 7.5g 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 (intravenously) as soon as possible.
Acetylcysteine: Acetylcysteine should be administered as soon as possible, preferably within 8 hours of overdosage.
IV: An initial dose of 150mg/ kg in 200ml glucose injection, given intravenously over 15minutes, followed by an intravenous infusion of 50mg/kg in 500ml glucose injection over the next 4hours, and then 100mg/kg in 1000ml over the next 16hours. The volume of intravenous fluids should be modified for children.
Orally: 140mg/kg as a 5% solution initially, followed by a 70mg/kg solution every 4 hours for 17 doses.
Acetylcysteine is effective if administered within 8hours of overdosage.
Ibuprofen: The most likely symptoms of overdosage are epigastric pain and nausea.
Codeine phosphate: Symptoms of overdosage include excitement and, in children, convulsions may occur. Large doses produce respiratory depression.
Treatment of overdosage is symptomatic and supportive.

IDENTIFICATION: A hard gelatin capsule with a green body and maroon cap, plain on body and cap.

PRESENTATION:
100s in HDPE round bottles with aluminium waded HDPE screw caps.
30s in HDPE round bottles with aluminium waded HDPE screw caps
30s in PVC-Aluminium blister packs.

STORAGE CONDITIONS
Do not store above 30°C. KEEP OUT OF THE REACH OF CHILDREN.

REGISTRATION NUMBER: TBA

NAME OF APPLICANT

VARICHEM
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