APPROVED NAME : CO-CODAMOL CAPLETS

TRADE NAME : GIGAPYN

REGISTRATION NUMBER:
TBA

PHARMACOLOGICAL CLASSIFICATION:
N02AJ Opioids in combination with non-opioid analgesics

DISTRIBUTION CATEGORY: Pharmacy Only

COMPOSITION: Each caplet contains the equivalent of 8 mg Codeine Phosphate and 500 mg paracetamol

IDENTIFICATION:
Capsule-shaped white caplet with a breakline on both sides and embossed 'P' on one half and 'C' on other half.

PHARMACOLOGICAL ACTION:
PARACETAMOL:
Has analgesic and antipyretic properties similar to aspirin and other nonsteroidal anti-inflammatory agents. It has the same potency as aspirin in inhibiting brain prostaglandin synthetase, but very little activity as an inhibition of the peripheral enzyme hence its weak anti-inflammatory action.

Paracetamol is rapidly and completely absorbed from the gastrointestinal tract reaching its peak plasma concentration 30 - 60 minutes after an oral dose with an elimination half-life of 1 - 3 hours. Distribution is wide crossing the placenta with little protein binding. It is metabolised in the liver and mainly excreted in urine as glucuronic acid (about 60 %), sulfuric acid (about 35 %) and cysteine (about 3 %) conjugates with 90 – 100 % being recovered in the urine as these conjugates. A small proportion undergoes cytochrome -p-450 mediated N-hydroxylation.

CODEINE PHOSPHATE:
Is a narcotic analgesic agent which interacts with stereospecific opiate receptors in the CNS and other tissues. Analgesia is produced primarily through an alteration in emotional response to pain. The relief of pain is fairly specific. Other sensory modalities are essentially unaffected and mental processes are not impaired, except when given in large doses or to unusually susceptible individuals.

Codeine is absorbed from the GIT reaching peak plasma concentrations in about an hour with a half life of 3 to 4 hours. It is metabolised in the liver and excreted in urine in largely inactive forms. A small fraction is demethylated to form norcodeine, other metabolites and morphine which is responsible for its analgesic effect with the antitussive action due to the codeine phosphate itself. Its conversion to morphine results in both morphine and its conjugates being detected in urine.

INDICATIONS
Gigapyn caplets are indicated for the relief of painful disorders such as headache, dysmenorrhoea, conditions involving musculoskeletal pain, myalgia and neuralgia. It is also indicated as an analgesic and antipyretic in conditions accompanied by discomfort and fever such as the common cold and viral infections. Gigapyn caplets are also an effective analgesic for dental pain

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REGISTRATION NUMBER:
Zimbabwe: 98/2.2/3439
Namibia: 13/2.8/0221
Malawi: PMPB/PL47/53

PHARMACOLOGICAL CLASSIFICATION:
2.2 ANALGESIC AND ANTIPYRETIC COMPOUND PRODUCTS

DISTRIBUTION CATEGORY: Zimbabwe: P
Namibia: NS2
Malawi: PIM

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CONTRAINDICATIONS
Hypersensitivity to Paracetamol or codeine, head injuries, asthmatic attacks, patients with hepatic diseases, impaired liver function, chronic cor pulmonale and hypertension.

PRECAUTIONS
Codeine phosphate may be habit forming. It may also cause drowsiness and caution should be taken when driving, operating machinery or performing other tasks requiring mental alertness. Prolonged use of codeine may cause constipation. Prolonged use of Paracetamol may lead to liver damage. Gigapyn caplets must be used with caution in patients with hepatic and renal diseases. Caution should be exercised when giving this medicine to asthmatics and hypertensive patients.

ADVERSE EFFECTS AND SPECIAL PRECAUTIONS
Codeine Phosphate - the most frequently observed adverse reactions include respiratory depression, light headedness, dizziness, sedation, nausea and vomiting, mental clouding, dysphoria, constipation, urinary retention, hypotension and decreased pressure in the biliary tract.
Paracetamol - side effects although rare include erythematous and urticarial rashes, renal tubular necrosis, hepatic necrosis, and hypoglycaemia.

DOSAGE AND ADMINISTRATION
Adults : 1 - 2 caplets, three to four times daily.
Children above 7 years : ½ - 1 caplet three or four times daily.
Not recommended for children under 7 years of age, unless under the advice of a doctor. Do not use continuously for more than 10 days without consulting your doctor.

OVERDOSAGE AND ITS TREATMENT
Overdosage presents as hepatic necrosis but laboratory evidence may be delayed for a week, nausea, vomiting, anorexia and abdominal pain present within the first 24 hours, depressed respiration, stupor, coma, pinpoint pupils, hypotension, cold clammy skin, weak muscles and relaxed jaws may also present due to the Codeine Phosphate.
Gastric lavage or emesis must be performed preferably within 24 hours to limit absorption. The principal antidotal treatment is the administration of sulfhydryl compounds, N-acetylcysteine to replenish hepatic glutathione and an opioid antagonist naloxone. N-acetylcysteine is given as a loading dose of 140 mg/kg orally followed by 70 mg/kg every 4 hours for 17 doses. Naloxone is given in small doses of 0.4 mg to 2 mg i.v. repeated at intervals of 2 to 3 minutes to a maximum of
10 mg if no effect is observed.

PRESENTATION
In containers of 30's, 50's, 100's and 1000's (HDPE jar and LDPE closure, PP securitainer container and LDPE closure)
Push through blister packs of 10 caplets in a carton of 30's or 1000's.

STORAGE INSTRUCTIONS
Store in a dry place, below 25 ˚C, out of direct light. Keep out or reach of children.

MANUFACTURER
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