

SCHEDULING STATUS:

S5

PROPRIETARY NAME: STOPAYNE* CAPSULES

(and dosage form)

COMPOSITION:

Each capsule contains:

Paracetamol	320 mg
Codeine Phosphate	8 mg
Caffeine Anhydrous	48 mg
Meprobamate	150 mg

Contains TARTRAZINE.

PHARMACOLOGICAL CLASSIFICATION: A 2.8 Analgesic Combinations.

PHARMACOLOGICAL ACTION:

STOPAYNE* CAPSULES have analgesic, antipyretic and tranquillizing properties.

INDICATIONS:

STOPAYNE* CAPSULES relieve mild to moderate pain and fever, and pain associated with tension.

CONTRA-INDICATIONS:

Hypersensitivity to any of the active ingredients.

Should not be given to patients with acute intermittent porphyria or a history of epilepsy.

Contra-indicated in respiratory depression, especially in the presence of cyanosis and excessive bronchial secretion, after operations on the biliary tract, acute alcoholism, head injuries and

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conditions in which intracranial pressure is raised. It should not be given during an attack of bronchial asthma or in heart failure secondary to chronic lung disease.

Contra-indicated in patients taking monoamine oxidase inhibitors or within fourteen days of stopping such treatment.

WARNINGS:

STOPAYNE* CAPSULES are not recommended for use by pregnant or breastfeeding women.

Paracetamol dosages in excess of those recommended may cause severe liver damage.

Contains tartrazine which may cause allergic type reactions (including bronchial asthma) in certain individuals. The overall incidence of tartrazine sensitivity is low; it is however frequently seen in patients who also have aspirin sensitivity.

DOSAGE AND DIRECTIONS FOR USE:

Adult dosage: Two capsules three or four times a day as required. Do not use continuously for more than ten days without consulting your doctor.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

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

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

Sensitivity reactions resulting in reversible skin rash or blood disorders may occur.

The use of this medicine may cause drowsiness and care should be taken when driving or operating machinery. Reduce dosage if necessary.

Patients receiving meprobamate should be warned that their tolerance to ingested alcohol and other depressants of the central nervous system may be lowered with consequent impairment of judgement and co-ordination.

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

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, impaired liver 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, sedatives, and phenothiazines.

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

The most frequent side-effect of meprobamate is drowsiness. Other effects include nausea, vomiting, diarrhoea, paraesthesia, weakness, headache, excitement, dizziness, ataxia and disturbances of vision. Hypotension, tachycardia and cardiac arrhythmias may occur.

Hypersensitivity reactions may occur. They may be limited to skin rashes, urticaria and purpura or may be more severe with angioneurotic oedema, bronchospasm or anuria. Erythema multiforme has been reported. Blood disorders including agranulocytosis, eosinophilia, leucopenia, thrombocytopenia and aplastic anaemia have been reported. Symptoms of porphyria may be exacerbated.

Prolonged use of meprobamate may lead to the development of dependence of the barbiturate-alcohol type.

Meprobamate may induce the hepatic microsomal enzymes involved in drug metabolism.

Caffeine may cause restlessness, excitement, muscle tremor, tinnitus, scintillating scotoma, tachycardia and extrasystoles. Caffeine increases gastric secretions and may cause gastric ulceration. Caffeine should be given with care to patients with a history of peptic ulceration.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

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. The latest information regarding the treatment of overdosage can be obtained from the nearest poison information centre. Symptoms of overdosage include nausea and vomiting. Liver damage, which may be fatal, may only appear after a few days. Kidney failure has been described following acute intoxication.

Acute meprobamate overdosage can produce stupor, coma, convulsions, shock, circulatory and respiratory collapse. Because meprobamate is rapidly absorbed from the gastro-intestinal tract, gastric lavage must be carried out shortly after ingestion and must be thorough.

IDENTIFICATION:

Green/white two coloured capsules. RIO marked on each half.

PRESENTATION:

Packaged in push-through blister packs of 100 capsules.

STORAGE INSTRUCTIONS:

Keep in a safe place, out of reach of children. Store below 25 °C. Protect from light and moisture.

REGISTRATION NUMBER: C/2.8/15

ADCOCK INGRAM LIMITED

STOPAYNE CAPSULES

Amended: 10/08/1999

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NAME AND BUSINESS ADDRESS OF THE APPLICANT:

ADCOCK INGRAM LIMITED

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