PROFESSIONAL INFORMATION

SCHEDULING STATUS

S5

1. NAME OF THE MEDICINE

STOPAYNE TABLETS, tablets.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Meprobamate	150 mg
Codeine phosphate	8 mg
Paracetamol	320 mg
Caffeine anhydrous	32 mg

Excipients with known effect:

Contains sugar (lactose monohydrate): 1 mg

Contains the colouring agent sunset yellow FCF (E 110).

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets.

Light green, round biconvex tablets, scored on one side and RIO embossed on the other side.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Posology

DO NOT EXCEED THE RECOMMENDED DOSE.

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

Special populations

No information available.

Paediatric population

No information available.

Method of administration

Oral.

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4.3 Contraindications

- Hypersensitivity to any of the active ingredients or to any of the excipients of STOPAYNE TABLETS (see section 2 and section 6.1),
- STOPAYNE TABLETS should not be given to patients with acute intermittent porphyria or a history of epilepsy,
- respiratory depression especially in the presence of cyanosis and excessive bronchial secretion,
- after operations on the biliary tract,
- acute alcoholism,
- head injuries and conditions in which intracranial pressure is raised,
- during an attack of bronchial asthma,
- heart failure secondary to chronic lung disease,
- in patients taking monoamine oxidase inhibitors or within fourteen days of stopping such treatment.

4.4 Special warnings and precautions for use

STOPAYNE TABLETS are not recommended for use by pregnant or breastfeeding women (see section 4.6).

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.

Paracetamol

This product contains paracetamol which may be fatal in overdose. In the event of overdosage or suspected overdose and notwithstanding the fact that the person may be asymptomatic, the nearest doctor, hospital or Poison Centre must be contacted immediately.

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

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

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Codeine

Exceeding the prescribed dose, together with prolonged and continuous use of this medication, may lead to dependency and addiction.

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.

Caffeine

Caffeine should be given with care to patients with a history of peptic ulceration.

Meprobamate

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.

Symptoms of porphyria may be exacerbated (see section 4.3). 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.

Contains the colouring agent sunset yellow (FCF) (E 110), which may cause allergic type reactions (including bronchial asthma) in certain individuals.

Contains lactose monohydrate which may have an effect on the glycaemic control of patients with diabetes mellitus.

Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take STOPAYNE TABLETS.

4.5 Interactions with other medicines and other forms of interaction

No information available.

Paediatric population

No information available.

4.6 Fertility, pregnancy and lactation

Pregnancy

STOPAYNE TABLETS is not recommended for use by pregnant women.

Breastfeeding

STOPAYNE TABLETS is not recommended for use by breastfeeding women.

Fertility

No information available.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

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

a. Summary of the safety profile

No information available.

b. Tabulated summary of adverse reactions

Codeine

SYSTEM ORGAN CLASS	ADVERSE REACTIONS
Psychiatric disorders	Changes of mood.
Nervous system disorders	Drowsiness, confusion, vertigo, restlessness, orthostatic hypotension and raised intracranial pressure may occur.
Eye disorders	Miosis.
Cardiac disorders	Bradycardia, palpitations.
Gastrointestinal disorders	Codeine may cause nausea, vomiting, constipation, and dry mouth.
Skin and subcutaneous tissue disorders	Sweating and facial flushing. Reactions such as urticaria and pruritus may occur.
Renal and urinary disorders	Micturition may be difficult and there may be ureteric or biliary spasm.
General disorders and administration site conditions	Hypothermia.

Caffeine

SYSTEM ORGAN CLASS	ADVERSE REACTIONS
Nervous system disorders	Caffeine may cause restlessness, excitement, muscle tremor.
Eye disorders	Scintillating scotoma.

Ear and labyrinth disorders	Tinnitus.
Cardiac disorders	Tachycardia and extrasystoles.
Gastrointestinal disorders	Caffeine increases gastric secretions and may cause gastric ulceration.

Meprobamate

SYSTEM ORGAN CLASS	**ADVERSE REACTIONS**
Blood and lymphatic system disorders	Blood disorders including agranulocytosis, eosinophilia, leukopenia, thrombocytopenia, and aplastic anaemia have been reported.
Nervous system disorders	The most frequent side effect of meprobamate is drowsiness. Paraesthesia, weakness, headache, excitement, dizziness, ataxia.
Eye disorders	Disturbances of vision.
Cardiac disorders	Hypotension, tachycardia and cardiac arrhythmias may occur.
Gastrointestinal disorders	Nausea, vomiting, diarrhoea.
Skin and subcutaneous tissue disorders	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.

Post marketing experience

No information available.

c. Description of selected adverse reactions

No information available.

d. Paediatric population

No information available.

e. Other special population(s)

No information available.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

4.9 Overdose

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 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 gastrointestinal tract, gastric lavage must be carried out shortly after ingestion and must be thorough.

In paracetamol overdose prompt treatment is essential. A delay in starting treatment may mean that the antidote is given too late to be effective. Evidence of liver damage is often delayed until after the time for effective treatment has lapsed.

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Susceptibility to paracetamol toxicity is increased in patients who have taken repeated high doses (greater than 5 to 10 g/day) of paracetamol for several days, in chronic alcoholism, chronic liver disease, AIDS, malnutrition, and with the use of medicine that induce liver microsomal oxidation such as barbiturates, isoniazid, rifampicin, phenytoin and carbamazepine.

Symptoms of paracetamol overdosage in the first 24 hours include pallor, nausea, vomiting, anorexia, and possibly abdominal pain. Mild symptoms during the first two days of acute poisoning, do not reflect the potential seriousness of the overdosage.

Liver damage may become apparent 12 to 48 hours, or later after ingestion, initially by elevation of the serum transaminase and lactic dehydrogenase activity, increased serum bilirubin concentration and prolongation of the prothrombin time. Liver damage may lead to encephalopathy, coma and death.

Acute renal failure with acute tubular necrosis may develop even in the absence of sever liver damage. Abnormalities of glucose metabolism and metabolic acidosis may occur. Cardiac arrhythmias have been reported.

Treatment for paracetamol overdosage:

N-acetylcysteine should be administered to all cases of suspected overdose as soon as possible preferably within eight hours of overdosage, although treatment up to 36 hours after ingestion may still be of benefit, especially if more than 150 mg/kg of paracetamol was taken. An initial dose of 150 mg/kg N-acetylcysteine in 200 mL dextrose injection given **intravenously (IV)** over 15 minutes, followed by an infusion of 50 mg/kg in 500 mL dextrose injection over the next four hours, and then 100 mg/kg in 1 000 mL dextrose injection over the next sixteen hours. **The volume of intravenous fluid should be modified for children.**

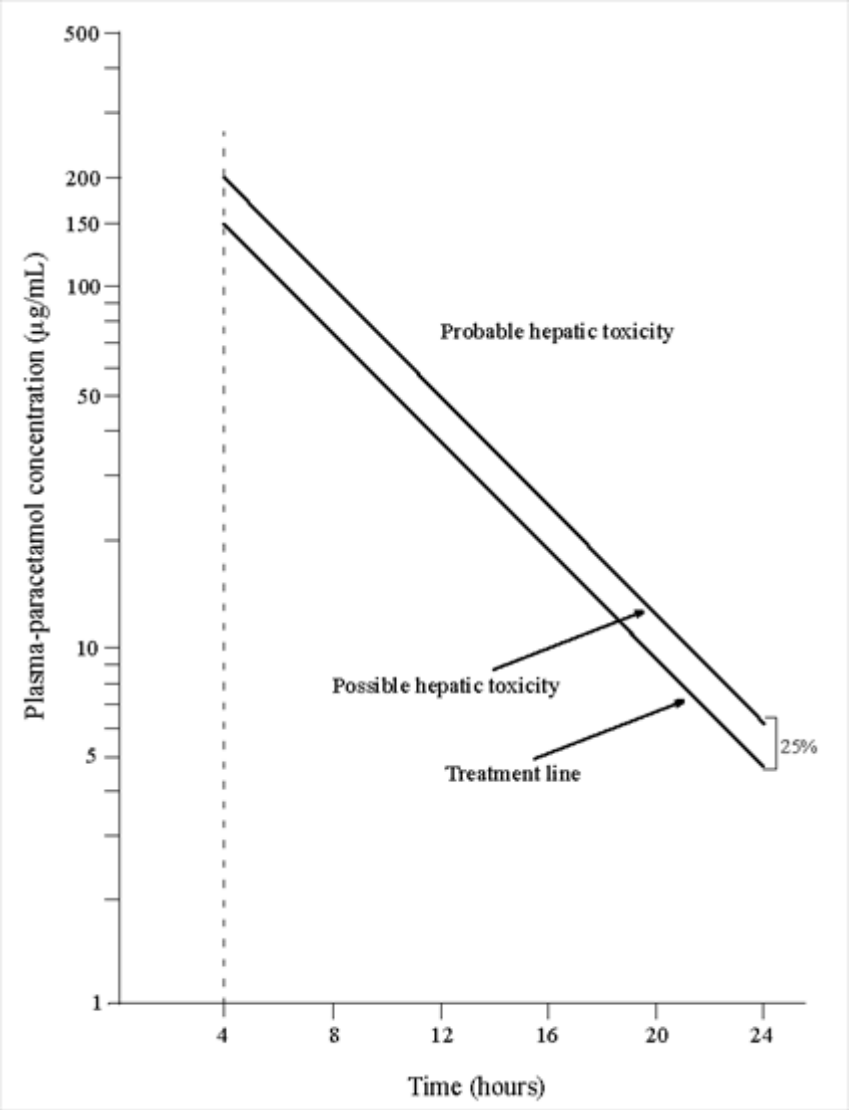
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Although the oral formulation is not the treatment of choice,
140 mg/kg dissolved in water may be administered initially, followed by 70 mg/kg every four hours for seventeen doses.

A plasma paracetamol level should be determined four hours after ingestion in all cases of suspected overdosage. Levels done before four hours may be misleading. Patients at risk of liver damage, and hence requiring continued treatment with N-acetylcysteine, can be identified according to their 4-hour plasma paracetamol level. The plasma paracetamol level can be plotted against time since ingestion in the nomogram below. The nomogram should be used only in relation to a single acute ingestion.

A semi-logarithmic plot of plasma-paracetamol concentration against hours after ingestion.

Reference: Martindale, The Complete Drug Reference.



Those whose plasma paracetamol levels are above the “normal treatment line”, should continue N-acetylcysteine treatment with 100 mg/kg IV over sixteen hours repeatedly until recovery. Patients with increased susceptibility to liver damage as identified above, should continue treatment if concentrations are above the “high risk treatment line”. Prothrombin index correlates best with survival.

For overdose with an extended/modified release preparation the value of the nomogram is unknown. As there is no information on the plasma levels of paracetamol after an overdose of extended/modified release paracetamol preparations, all patients with suspected or known overdose with such preparations should receive N-acetylcysteine. Because of lack of data for extended/modified release

formulations, a level below the “treatment line” of the nomogram may not exclude the possibility of toxicity.

Monitor all patients with significant ingestions for at least ninety-six hours.

5. PHARMACOLOGICAL PROPERTIES

Category and class: A 2.8 Analgesic combinations.

STOPAYNE TABLETS have analgesic, antipyretic and tranquilising properties.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Brilliant blue FCF (E133)

Gelatine.

Lactose monohydrate.

Magnesium stearate.

Povidone.

Pregelatinized starch.

Purified talc.

Quinoline yellow (E104).

Sodium starch glycolate.

Sunset yellow FCF (E110).

6.2 Incompatibilities

No data available.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store at or below 25 °C.

Protect from light and moisture.

6.5 Nature and contents of container

PVC/PVDC/Aluminium blister strips in an outer carton.

or

White HDPE bottles with white HDPE screw caps.

Pack sizes: 100 or 1 000 tablets. Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Adcock Ingram Limited

Address

1 New Road

Erand Gardens

Midrand

1685

Customer Care: 0860 ADCOCK / 232625

8. REGISTRATION NUMBER(S)

B 866 (Act 101/1965)

PROFESSIONAL INFORMATION

Namibia	NS3	14/2.8/0417

Botswana	S1	B9300805

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of registration: 19 November 1986

10. DATE OF REVISION OF THE TEXT

29 October 2021