PROFESSIONAL INFORMATION

SCHEDULING STATUS:

S0 **Pack sizes equal to or smaller than 25 tablets**

S1 **Pack sizes larger than 25 tablets**

1. NAME OF THE MEDICINE

ADCO-NAPAMOL TABLETS

Strength

Each tablet contains:

Paracetamol	500 mg

Pharmaceutical form:

Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Paracetamol	500 mg
Preservative:	
Potassium sorbate	0,12 *% m/m*

Sugar free

For a full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

White to off white**,** round, flat, beveled edge tablet with a score line on one side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the symptomatic treatment of mild to moderate pain and fever.

4.2 Posology and method of administration

Adults and children over 12 years of age: 1 to 2 tablets orally every 4 to 6 hours as required but not more than 8 tablets to be taken daily.

Children 6 to 12 years: ½ to 1 tablet given orally 3 to 4 times daily as required. Not more than 4 doses daily.

DO NOT EXCEED THE RECOMMENDED DOSE.

4.3 CONTRAINDICATIONS:

Hypersensitivity to any of the ingredients. Patients with severe liver function impairment.

4.4 Special warnings and precautions for use

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.

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 a doctor if no relief is obtained from the recommended dosage. Do not administer to children under 6 years of age. Do not use continuously for more than 10 days without consulting a doctor.

4.5 Interactions with other medicines and other forms of interactions

None.

4.6 Fertility, pregnancy and lactation:

Safety and/or efficacy has not been established.

4.7 Effects on ability to drive and use of machines

The effects on the ability to drive and use machines has not been established.

4.8 Undesirable effects

Frequency	**System organ classification**	**Side effects**
Frequency unknown	Blood and lymphatic system disorders	Pancytopenia, neutropenia, leucopenia, thrombocytopenia and agranulocytosis
	Gastrointestinal disorders	Pancreatitis
	General disorders and administration site conditions	Drug fever
	Skin and subcutaneous tissue disorders	Skin rashes with urticaria and erythema

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. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the **"6.04 Adverse Drug Reactions**

Reporting Form" found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8 **.**

May also report to Adcock Ingram Limited using the following email:

Adcock.AEReports@adcock.com

4.9 Overdose

Prompt treatment is essential. In the event of an overdosage, consult a doctor immediately, or take the person directly to a hospital. A delay in starting treatment may mean that antidote is given too late to be effective. Evidence of liver damage is often delayed until after the time for effective treatment has lapsed. Susceptibility to paracetamol toxicity is increased in patients who have taken repeated high doses (greater than 5 -10 g/day) of paracetamol for several days, in chronic alcoholism, chronic liver disease, AIDS, malnutrition, and with the use of drugs 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 severe liver damage. Abnormalities of glucose metabolism and metabolic acidosis may occur. Cardiac arrhythmias have been reported.

Treatment for paracetamol overdosage: Although evidence is limited it is recommended that any adult person who has ingested 5 - 10 grams or more of paracetamol (or a child who has had more than 140 mg/kg) within the preceding four hours, should have the stomach emptied by lavage (emesis may be adequate for children) and a single dose of 50 g activated charcoal given via the lavage tube. Ingestion of amounts of paracetamol smaller than this may require treatment in

patients susceptible to paracetamol poisoning (see above). In patients who are stuperose or comatose endotracheal intubation should precede gastric lavage in order to avoid aspiration.

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** 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**.

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.

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.

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

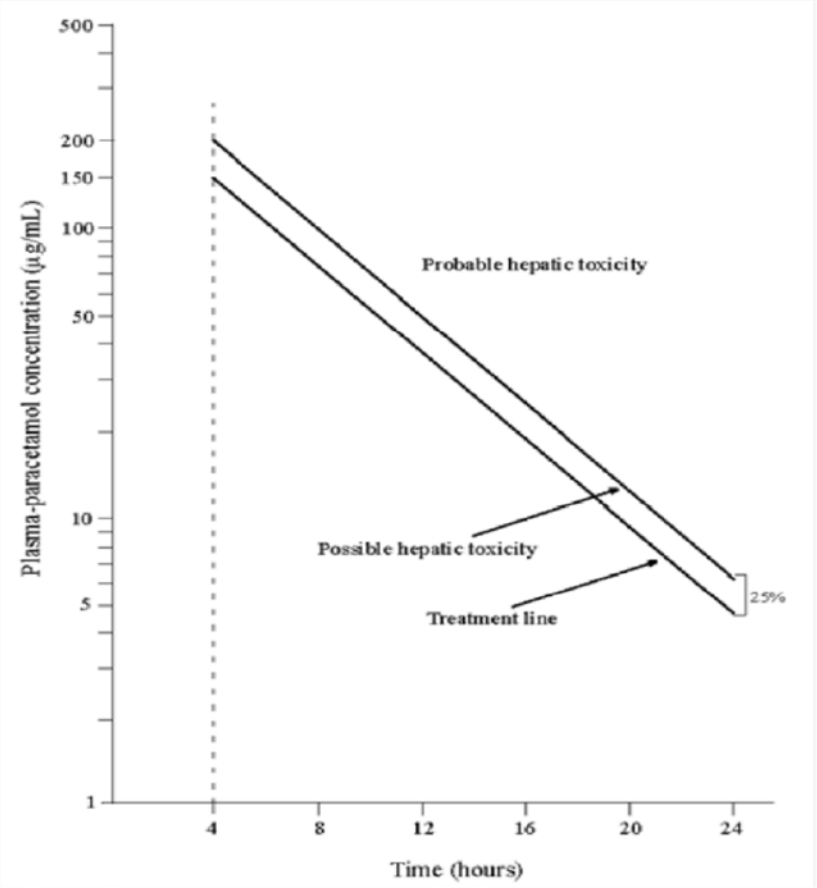

Figure 1. A semi-logarithmic plot of plasma-paracetamol concentration against hours after ingestion.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

A 2.7 Antipyretics or antipyretic and anti -inflammatory analgesics.

Mechanism of action

Paracetamol has analgesic and antipyretic properties.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Colloidal silica, magnesium stearate, maize starch.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 Months.

6.4 Special precautions for storage

Store at or below 25 °C. Protect from light and moisture.

6.5 Nature and contents of container

10, 20 and 100 tablets in aluminium foil/clear PVC blister packs. 5 000 tablets in square white HDPE buckets with white HDPE handles, natural HDPE closures & clear LDPE bags (with silica gel sachets).

Not all pack sizes above are necessarily marketed.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION:

Adcock Ingram Limited

1 New Road,

Erand Gardens,

Midrand, 1685

Customer Care: 0860ADCOCK (232625)

8. REGISTRATION NUMBER:

B/2.7/1404

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION

15 April 1991

10. DATE OF REVISION OF THE TEXT

30 September 2021

Botswana: BOT 1803272 S4
Namibia: NS0 90/2.8/00148

Bindia Naidoo Digitally signed by Bindia Naidoo