PROFESSIONAL INFORMATION

SCHEDULING STATUS:

S0

50 ml and 100 ml elixir

1. NAME OF THE MEDICINE

ADCO NAPAMOL ELIXIR,120 mg / 5 ml (Elixir)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml of ADCO NAPAMOL ELIXIR contains:

Paracetamol	120 mg
Alcohol	0,50 % v/v
Preservatives:	
Methylparaben	0,110 % m/v
Propylparaben	0,015 % m/v
Contains sugar:	
Sucrose	1,9644 g

For a full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

ELIXIR

A clear green liquid with an odour of peppermint

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

Posology

Children:	Not more than 4 doses daily.
6 to 12 years:	2 to 4 medicine measures elixir (10 to 20 ml) 3 to 4 times daily as required.
1 to 6 years:	1 to 2 medicine measures elixir (5 to 10 ml) 3 to 4 times daily as required.
3 months to 1 year:	½ to 1 medicine measure elixir (2,5 to 5 ml) 3 to 4 times daily as required.

DO NOT EXCEED THE RECOMMENDED DOSE

Method of administration

Oral administration.

4.3. Contraindications

- Hypersensitivity to paracetamol or any of the other ingredients (listed in section 6.1).
- Patients with severe liver function impairment.

4.4 Special warnings and precautions for use

ADCO NAPAMOL ELIXIR 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 of ADCO NAPAMOL ELIXIR in excess of those recommended may cause severe liver damage.

Consult a medical practitioner if pain or fever persists or gets worse at the recommended dosage, if new symptoms occur or if redness and swelling is present, as these could be signs of a more serious condition.

Do not use continuously for more than 10 days without consulting a doctor.

ADCO NAPAMOL ELIXIR contains sucrose. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose mal-absorption or sucrase-isomaltase insufficiency should not take ADCO NAPAMOL ELIXIR.
ADCO NAPAMOL ELIXIR contains sucrose which may have an effect on the glycaemic control of patients with diabetes mellitus.

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

Patients suffering from hepatitis or alcoholism, or recovering from any form of liver disease, should not take excessive quantities of ADCO NAPAMOL ELIXIR**.**

Use with caution in renal disease, alcohol dependence, chronic malnutrition, or dehydration**.**

ADCO-NAPAMOL ELIXIR contains glycerol and may have a laxative effect.

High Anion gap metabolic acidosis (HAGMA)

High Anion gap metabolic acidosis (HAGMA) Caution is advised if ADCO NAPAMOL ELIXIR is administered concomitantly with flucloxacillin due to increased risk of high anion gap metabolic acidosis (HAGMA), particularly in patients with severe renal impairment, sepsis, malnutrition, and other sources of glutathione deficiency (e.g. chronic alcoholism), as well as those using maximum daily doses of ADCO NAPAMOL ELIXIR. Close monitoring, including measurement of urinary 5-oxoproline, is recommended.

Severe cutaneous adverse reactions (SCARs)

Severe cutaneous adverse reactions (SCARs) such as toxic epidermal necrolysis (TEN), Steven-Johnson syndrome (SJS), acute generalized exanthematous pustulosis (AGEP), eosinophilia and systemic (DRESS)/ Drug-induced hypersensitivity syndrome (DIHS) and fixed drug eruptions (FDE) have been reported in patients treated with paracetamol containing medicines. If a patient develops SCAR, treatment with ADCO NAPAMOL ELIXIR must immediately be discontinued and appropriate treatment instituted (see Section 4.8).
Consult a doctor if no relief is obtained from the recommended dosage.

4.5 Interactions with other medicines and other forms of interactions

Hepatotoxic and enzyme-inducing medicines: The risk of paracetamol toxicity may be increased in patients receiving other potentially hepatotoxic medicines or medicines that induce liver microsomal enzymes. Possible decrease in therapeutic effect of ADCO NAPAMOL ELIXIR.

Metoclopramide: The absorption of ADCO NAPAMOL ELIXIR may be accelerated.

Cholestyramine: Reduces the absorption of ADCO NAPAMOL ELIXIR if given within one hour of paracetamol.

Probenecid: Urinary excretion of the sulphate and glucuronide conjugates of paracetamol are reduced while urinary excretion of paracetamol remain unchanged. Pre-treatment with probenecid can decrease paracetamol clearance and increase its plasma half-life.

Antibiotics: Severe hepatotoxicity at therapeutic doses of ADCO NAPAMOL ELIXIR or moderate overdoses of ADCO NAPAMOL ELIXIR may result in patients receiving *isoniazid*, alone or with other drugs for tuberculosis. The plasma-paracetamol concentrations considered an indication for antidote treatment should be halved in patients receiving enzyme inducing drugs such as rifampicin.

Salicylates: Prolonged combined use of ADCO NAPAMOL ELIXIR with salicylates increases the risk of adverse renal effects.

Warfarin and Anticoagulants: Concurrent, chronic, high-dose administration of ADCO NAPAMOL ELIXIR may increase the anticoagulant effect. Since paracetamol is recommended as the general analgesic and antipyretic of choice in patients on oral anticoagulant therapy, caution is needed. Increased monitoring of anticoagulant therapy may be appropriate for those also taking paracetamol regularly.

Antiepileptics: The plasma-paracetamol concentrations considered an indication for antidote treatment should be halved in patients receiving enzyme inducing drugs such as carbamazepine, phenobarbital, phenytoin, or primidone.

Antivirals: Severe hepatotoxicity has occurred after use of paracetamol in a patient taking zidovudine. However, neither short-term nor long-term studies (the latter also in an individual patient) have shown any alteration of zidovudine elimination in patients taking zidovudine and paracetamol.

Paracetamol has also been found to enhance the antiviral effect of interferon Alfa.

Interferon alfa: Paracetamol, as in ADCO NAPAMOL ELIXIR, has also been found to enhance the antiviral effect of interferon alfa.

Flucloxacillin: Caution should be taken when ADCO-NAPAMOL ELIXIR is used concomitantly with flucloxacillin as concurrent intake has been associated with high anion gap metabolic acidosis, especially in patients with risks factors (see **Section 4.4**).

4.6 Fertility, pregnancy, and lactation

Safety and efficacy in pregnancy and lactation has not been established. No data available on fertility.

4.7 Effects on ability to drive and use machines

ADCO-NAPAMOL ELIXIR has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

System Organ classification	**Frequency**	**Side effects**
Blood and lymphatic system disorders	Less frequent	• Pancytopenia; • Neutropenia; • Leucopenia; • Thrombocytopenia; • Agranulocytosis; • Anaemia.
Metabolism and nutrition disorders	Frequency unknown	• Pyroglutamic aciduria (5-oxoprolinuria); • High-anion gap metabolic acidosis.

Ear and labyrinth disorders	Frequency unknown	• Hearing loss.
Cardiac disorders	Frequency unknown	• Possible increase in the risk of hypertension.
Renal and urinary disorders	Less frequent	• Renal colic; • Renal failure; • Sterile pyuria.
	Frequency unknown	• Nephropathy.
Hepatobiliary disorders	Less frequent	• Hepatitis.
Gastrointestinal disorders	Less frequent	• Pancreatitis.
	Frequency unknown	• Nausea; • Vomiting.
General disorders and administration site conditions	Frequency unknown	• Drug fever; • Hypersensitivity reactions characterized by urticaria, dyspnea, and hypotension.
Skin and Subcutaneous tissue disorders	Frequency unknown	• Skin rashes with urticaria and erythema; • Dermatitis; • Other allergic reactions such as Steven Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TENS) and Acute Generalised Exanthematous Pustulosis (AGEP), Fixed drug eruptions (FDE) (see Section 4.4).
Immune system disorders	Frequency unknown	• drug-induced hypersensitivity syndrome (DIHS), Hypersensitivity reactions

		characterised by urticaria, dyspnoea, and hypotension (see Section 4.4).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

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 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.

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 are pallor, nausea, vomiting, anorexia, and 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. Cerebral oedema and non-specific myocardial depression have also occurred.

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:

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.

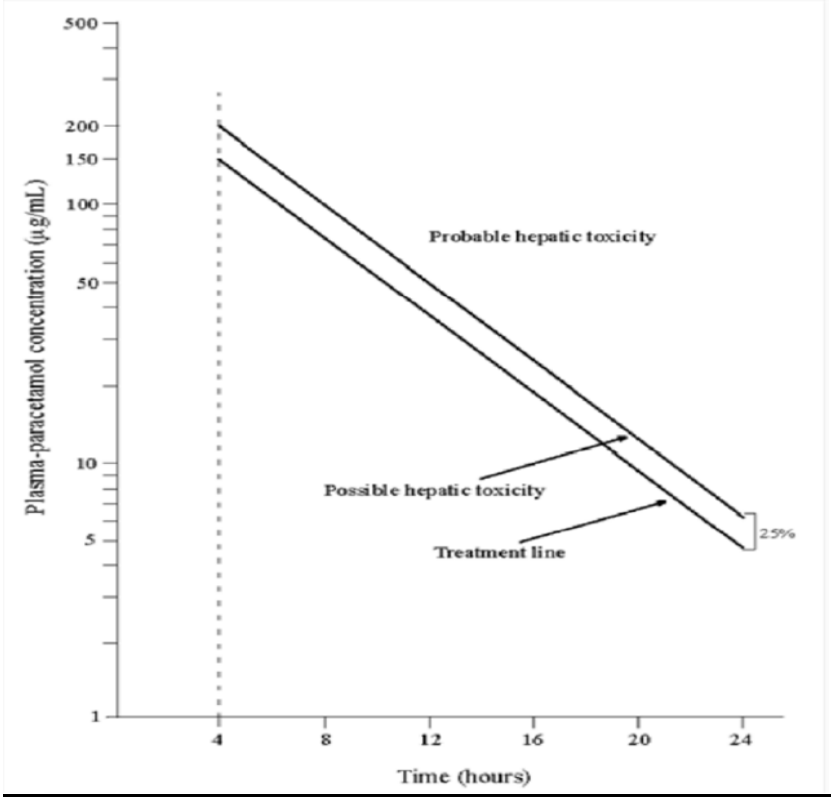


Figure 1. A semi-logarithmic plot of plasma-paracetamol concentration against hours after ingestion.

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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

A 2.7 Anti-pyretic or anti-pyretic and anti-inflammatory analgesics

Mechanism of action:

Paracetamol has analgesic and antipyretic properties.

5.2 Pharmacokinetics

Absorption: Following oral administration, paracetamol is well absorbed, with peak plasma concentrations obtained after 0, 5 to 1 hour. The plasma half-life is about 2 hours.

Distribution: Plasma protein binding is variable. Paracetamol is distributed into most body tissues. It crosses the placenta and is present in breast milk.

Elimination: Paracetamol is metabolised in the liver primarily by conjugation with glucuronic acid (about 60 %), sulphuric acid (about 35 %) and cysteine (about 3 %). Paracetamol is renally excreted primarily as conjugated metabolites.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Brilliant blue (colour blue F, D & C No.1), citric acid anhydrous, flavour vanillin, glycerol, ethanol 96,0 %, oil peppermint chinese ZD44699, polyvinylpyrrolidone K25, propylene glycol, sodium citrate dihydrate, spectracol quinolone yellow PSU8810.

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.

6.5 Nature and contents of container

50 ml and 100 ml in amber PVC bottles. 100 ml PET bottle with a screw on cap.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand, 1685

Customer Care: 0860 ADCOCK/232625

8. REGISTRATION NUMBER

B/2.7/1409

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF AUTHORIZATION

15 April 1991

10. DATE OF REVISION OF THE TEXT

06 February 2025

Namibia: NS1 05/2.7/0248
Botswana: S3 BOT1803271