PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S0**

50 ml and 100 ml elixir

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

Paracetamol

Alcohol 0,50 % *v/v*

Preservatives:

Methylparaben 0,110 % *m/v*

Propylparaben 0,015 % *m/v*

Contains sugar:

Sucrose 1,9644 g

Read all of this leaflet carefully because it contains important information for you.

ADCO NAPAMOL ELIXIR is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use ADCO NAPAMOL ELIXIR carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ADCO NAPAMOL ELIXIR with any other person.
- Ask your pharmacist or healthcare provider if you need more information or advice.
- You must see a doctor if your child's symptoms worsen or do not improve after 10 days.

What is in this leaflet

1. What ADCO NAPAMOL ELIXIR is and what it is used for
2. What you need to know before you take ADCO NAPAMOL ELIXIR

3. How to take ADCO NAPAMOL ELIXIR
4. Possible side effects
5. How to store ADCO NAPAMOL ELIXIR
6. Contents of the pack and other information

1. What ADCO NAPAMOL ELIXIR is and what it is used for

A 2.7 Anti-pyretic (medicine to reduce fever) or anti-pyretic and anti-inflammatory analgesics (medicine to reduce and relieve fever, inflammation and pain).

Paracetamol has analgesic (pain relief) and antipyretic (fever reducing) properties.
ADCO NAPAMOL ELIXIR is a medication containing paracetamol, therefore it is used to treat pain and fever.

2. What you need to know before you use ADCO NAPAMOL ELIXIR

Do not use ADCO NAPAMOL ELIXIR

- if your child is hypersensitive (allergic) to paracetamol or any of the above listed ingredients of ADCO NAPAMOL ELIXIR or to any of the other ingredients of ADCO NAPAMOL ELIXIR (listed in section 6).
- if your child's liver function is severely weakened or damaged.

Warnings and precautions

Special care should be taken with ADCO NAPAMOL ELIXIR:

ADCO NAPAMOL ELIXIR contains paracetamol, which may be fatal in overdose. In the event of overdosage or suspected overdose, even if your child is not showing or experiencing any symptoms, the nearest doctor, hospital, or Poison Centre must be contacted immediately.

- If you give your child more than the recommended dosage, as excess doses of paracetamol may cause severe liver damage.
- Ensure the correct dosage of ADCO NAPAMOL ELIXIR is given to your child.
- If your child is suffering from liver or kidney disease, contact your doctor before using ADCO NAPAMOL ELIXIR.
- If your child suffers from hepatitis (disease of the liver) or recovering from any form of liver disease, do not give excessive quantities of ADCO NAPAMOL ELIXIR.
- Use with caution if your child has kidney disease, chronic malnutrition or dehydration or if your child has not eaten in a few days.
- if you have been told by your doctor that your child has an intolerance to some sugars, contact your doctor before using ADCO NAPAMOL ELIXIR.
- ADCO NAPAMOL ELIXIR contains sucrose, which may have an effect on the control of your child's blood sugar. If your child has diabetes mellitus, consult your doctor before using ADCO NAPAMOL ELIXIR.
- Consult your doctor if no relief is obtained from the recommended dosage.
- Do not give your child ADCO NAPAMOL ELIXIR continuously for more than 10 days without consulting a doctor.
- Contains glycerol and may have a laxative effect.
- Use with caution if ADCO-NAPAMOL ELIXIR is administered together with flucloxacillin due to increased risk of high anion gap metabolic acidosis (HAGMA), particularly if your

child is suffering from severe renal impairment, sepsis, malnutrition, and other sources of glutathione deficiency, as well as if you are giving your child maximum daily doses of ADCO-NAPAMOL ELIXIR. Close monitoring is recommended.

- Serious skin reactions 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 receiving paracetamol. If your child experiences any signs of serious skin reactions such as swelling, itching, red severe rash, stop using ADCO NAPAMOL ELIXIR immediately and contact your doctor (see Section 4).

Other Medicines and ADCO NAPAMOL ELIXIR

Always tell your healthcare professional if your child is taking any other medicine. (This includes all complementary or traditional medicines).

In particular, ADCO NAPAMOL ELIXIR can affect the following medicines:

- **Hepatotoxic medicines** (Medicines that cause liver injury or damage): the risk of paracetamol toxicity may be increased if your child is receiving other medicines that cause liver injury or damage.
- **Enzyme-inducing medicines** (Medicines that increase metabolic activity of enzymes): possible decrease in the effectiveness of ADCO NAPAMOL ELIXIR.
- **Metoclopramide** (Medicine used to treat and prevent nausea): the absorption of ADCO NAPAMOL ELIXIR may be increased.
- **Cholestyramine** (Medicine used to lower high cholesterol levels in the blood): reduces the absorption of ADCO NAPAMOL ELIXIR if given within one hour of paracetamol.

- **Probenecid** [Medicine used to remove extra uric acid (waste product found in the blood) from the body to prevent the occurrence of gout and arthritis]: decreased paracetamol clearance.
- **Antibiotics** (Medicines used to fight infections caused by bacteria): severe liver damage at therapeutic doses of ADCO NAPAMOL ELIXIR may result in patients taking tuberculosis medicines.
- **Salicylates** (Medicines derived from salicylic acid used for the relieve of pain, reduce inflammation and lower fever): prolonged combined use with ADCO NAPAMOL ELIXIR increases the risk of adverse kidney effects
- **Warfarin and Anticoagulants** (Medicines used to treat or decrease blood clots in the blood vessels and the heart): increased anticoagulant effect with concurrent, chronic high-dose administration.
- **Antiepileptics** (Medicine use to treat epilepsy); increased paracetamol concentrations in the blood and plasma.
- **Antivirals** (Medicines used to treat infections caused by virus): severe liver damage has occurred after use in a patient taking zidovudine. Paracetamol has also been found to increase the antiviral effect of interferon Alfa.
- **Interferon alfa** (Medicine used to treat cancer as well as other virus infections)**:** Paracetamol, as in ADCO NAPAMOL ELIXIR, has also been found to enhance the antiviral effect of interferon alfa.
- **Flucloxacillin** (medicine used to fight infections caused by bacteria): concomitant use with ADCO NAPAMOL ELIXIR has been associated with high anion gap metabolic acidosis, especially in patients with risks factors (see **Warnings and precautions** above).

ADCO NAPAMOL ELIXIR with food and, drink and alcohol

ADCO NAPAMOL ELIXIR has no known interactions with food and drinks.

Pregnancy and, breastfeeding and fertility

Safety and/or efficacy in pregnancy, breastfeeding and fertility has not yet been established. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before using this medicine.

Driving and using machines

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

ADCO NAPAMOL ELIXIR contains sucrose

This may have an effect on the control of your child's blood sugar. if your child has diabetes mellitus, consult your doctor before using ADCO NAPAMOL ELIXIR.

ADCO NAPAMOL ELIXIR contains alcohol

The effect of the amount of alcohol that is in this medicine in children are not likely to be noticeable.

ADCONAPAMOL ELIXIR contains glycerol

Glycerol may have a laxative effect.

3. How to use ADCO NAPAMOL ELIXIR

Do not share medicines prescribed for your child with any other person.

Always use ADCO NAPAMOL ELIXIR exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are unsure.

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.

Give ADCO-NAPAMOL ELIXIR orally.

If you use more ADCO NAPAMOL ELIXIR than you should

- Symptoms of paracetamol overdosage in the first 24 hours include pallor, nausea, vomiting, anorexia, and possibly abdominal pain.
- Liver damage, which may be fatal, may only appear after a few days.
- Liver damage may cause disease of the brain, coma, and death.
- Acute kidney failure may develop even in the absence of severe liver damage.
- Abnormalities of glucose breakdown and metabolic acidosis (acid build up in the body) may occur.
- Irregular heartbeats have been reported.
- In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control center immediately.

If you forget to use ADCO NAPAMOL ELIXIR

Do not give your child a double dose to make up for forgotten individual doses.

4. Possible side effects

ADCO NAPAMOL ELIXIR can have side effects.

Not all side effects reported for ADCO NAPAMOL ELIXIR are included in this leaflet. Should your child's general health worsen or if your child experiences any untoward effects while taking ADCO NAPAMOL ELIXIR, please consult your health care provider for advice.

If any of the following happens, stop giving ADCO NAPAMOL ELIXIR, and tell your doctor immediately or go to the casualty department at your nearest hospital:

- chest pains,
- angina,
- changes in the way your heart beats, for example, if you notice it beating faster,
- difficulty breathing,
- signs of recurrent infections such as fever or sore throat,
- less urine than is normal, yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems,
- Mouth ulcers, cold sores and ulcers or soreness of your tongue,
- Skin lumps or hives (raised, red or white, itchy patches of skin),
- Blisters on your skin or inside your mouth, nose, vagina or bottom,
- The appearance of a rash or sunburn when you have been outside (even on a cloudy day),
- swelling of the eyelids, face, tongue or lips,
- severe dizziness,
- Serious skin reactions such as swelling, itching, red severe rash especially those covering your whole body (appearing as allergic wheals), stop giving ADCO NAPAMOL ELIXIR immediately and contact your doctor (see Section 2).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor immediately if you notice any of the following:

Less frequent side effects:

- Pancytopenia (Blood condition),
- Neutropenia (Blood condition),
- Leucopenia (Blood condition),
- Thrombocytopenia (Blood condition),
- Agranulocytosis (Blood condition),
- Anaemia (Blood deficiency),
- Renal colic (Pain due to blockage by kidney stones),
- Renal failure (Kidney failure),
- Sterile pyuria (White blood cells in the urine),
- Hepatitis,
- Pancreatitis.

Frequency unknown side effects:

- Pyroglutamic aciduria (5-oxoprolinuria) (Inability of the body to produce glutathione),
- High-anion gap metabolic acidosis (A condition that result when the body produces too much acid),
- Hearing loss,
- Possible increase in the risk of hypertension,
- Nephropathy (Deterioration of kidney function),
- Nausea,
- Vomiting,
- Drug fever,
- Hypersensitivity reactions characterized by urticarial (rash), dyspnea (difficulty breathing), and hypotension,
- Dermatitis (Dry, swollen and discolored skin),
- Steven Johnson Syndrome (Disorder of the skin and mucus membrane),
- Toxic Epidermal Necrolysis (Potentially life-threatening condition characterised by exfoliation of the skin and mucous membrane), Acute Generalised Exanthematous

Pustulosis (Severe skin adverse reaction).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If your child gets side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ADCO NAPAMOL ELIXIR.

May also report to Adcock Ingram Limited using the following email: Adcock.AEReports@adcock.com

5. How to store ADCO NAPAMOL ELIXIR

Store all medicines out of reach of children.

Store at or below 25 ºC in a cool, dry place.

Protect from light.

Do not store in bathrooms.

Do not use after the expiry date stated on the packaging.

Do not use ADCO NAPAMOL ELIXIR if you notice any visible signs of deterioration.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

KEEP OUT OF REACH OF CHILDREN

6. Contents of the pack and other information

What ADCO NAPAMOL ELIXIR contains

The active substances are:

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

The other ingredients are Brilliant blue (colour blue F, D & C No.1), citric acid anhydrous, flavour vanillin; glycerol; oil peppermint chinese ZD44699; polyvinylpyrrolidone K25; propylene glycol; sodium citrate dihydrate; spectracol quinolone yellow PSU8810.

What ADCO NAPAMOL ELIXIR looks like and contents of the pack

ADCO NAPAMOL ELIXIR is a clear green liquid with an odour of peppermint.

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

Holder of Certificate of Registration

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand, 1685

Customer Care: 0860 ADCOCK/232625

This leaflet was last revised in

06 February 2025

Registration number

B/2.7/1409

Access to the corresponding professional information

It is contained in the packaging of the medicine

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