PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

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

S1 **Pack sizes larger than 25 tablets**

ADCO-NAPAMOL TABLETS

Each tablet contains:

Paracetamol 500 mg

Sugar free

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

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

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

What is in this leaflet:

1. What ADCO-NAPAMOL TABLETS is and what it is used for
2. What you need to know before you take ADCO-NAPAMOL TABLETS
3. How to take ADCO-NAPAMOL TABLETS
4. Possible side effects
5. How to store ADCO-NAPAMOL TABLETS
6. Contents of the pack and other information

1. What ADCO-NAPAMOL TABLETS is and what it is used for

ADCO-NAPAMOL TABLETS is an analgesic medication containing paracetamol used to treat mild to moderate pain and fever.

2. What you need to know before you take ADCO-NAPAMOL TABLETS

Do not take ADCO-NAPAMOL TABLETS:

- if you are hypersensitive (allergic) to paracetamol or any of the other ingredients of ADCO-NAPAMOL TABLETS (listed in section 6).
- if your liver function is severely impaired.

Warnings and precautions

Take special care:

- as 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.
- if you take more than the recommended dosage, as excess doses of Paracetamol may cause severe liver damage.
- if you have liver or kidney disease.
- to not administer to children under 6 years of age.
- Consult a doctor if no relief is obtained from the recommended dosage. Do not use continuously for more than 10 days without consulting a doctor.

Children and adolescents

Do not give ADCO-NAPAMOL TABLETS to children younger than 6 years old.

Other Medicines and ADCO-NAPAMOL TABLETS

Always tell your health care professional if you are taking any other medicine, including complementary or traditional medicines.

ADCO-NAPAMOL TABLETS with food and drinks

ADCO-NAPAMOL TABLETS has no known interactions with food and drinks.

Pregnancy, breastfeeding and fertility

Safety in fertility, pregnancy and lactation has not 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 health care professional for advice before taking this medicine.

Driving and using machines

The effects on ability to drive and use of machines has not been established. It is not always possible to predict to what extent ADCO-NAPAMOL TABLETS may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ADCO-NAPAMOL TABLETS affects them.

3. How to take ADCO-NAPAMOL TABLETS

Do not share medicines prescribed for you with any other person.

Always take ADCO-NAPAMOL TABLETS exactly as described in this leaflet or as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are unsure.

Adults and children over 12 years of age: 1 to 2 tablets orally every 4 to 6 hours when necessary (only take a maximum of 8 tablets in 24 hours).

Children 6 to 12 years: ½ to 1 tablet given orally every 3 to 4 times daily when necessary (only to take a maximum of 4 tablets in 24 hours).

DO NOT EXCEED THE RECOMMENDED DOSE

If you take more ADCO-NAPAMOL TABLETS 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. 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 take ADCO-NAPAMOL TABLETS

Do not take / receive a double dose to make up for forgotten individual doses.

4. Possible side effects

ADCO-NAPAMOL TABLETS can have side effects.

Not all side effects reported for ADCO-NAPAMOL TABLETS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ADCO-NAPAMOL TABLETS, please consult your health care provider for advice.

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

Frequency not known:

- Skin rashes
- Itchy skin
- Severe redness of the skin
- Sudden spike in fever after taking a dose
- Blood cell disorders
- Inflammation of the pancreas

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice. If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects 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*. By reporting side effects, you can help provide more information on the safety of ADCO-NAPAMOL TABLETS.

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

Adcock.AEReports@adcock.com

5. How to store ADCO-NAPAMOL TABLETS

Store all medicines out of reach of children.

Store at or below 25 ºC. Protect from light and moisture.

Do not store in bathrooms.

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

Do not use ADCO-NAPAMOL TABLETS 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).

6. Contents of the pack and other information

What ADCO-NAPAMOL TABLETS contains

The active substance is:

Paracetamol 500 mg

The other ingredients are:

Colloidal silica, magnesium stearate, maize starch, potassium sorbate 0.12*% m/m* (preservative).

What ADCO-NAPAMOL TABLETS looks like and contents of the pack

ADCO-NAPAMOL TABLETS are white to off white, round, flat tablet with beveled edges and a score line on one side. They come in 10, 20, 100 tablets in aluminium foil/clear PVC blister packs and 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 are necessarily marketed.**

Holder of Certificate of Registration

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This leaflet was last revised in

N/A – New leaflet

Registration number

B/2.7/1404

Namibia NS0 90/2.8/00148
Botswana BOT 1803272 S4

adcock ingram

1226240 042023