PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S3**

ADCO-NAPACOD TABLETS

Each tablet contains:

Codeine phosphate 10 mg

Paracetamol 500 mg

Sugar free

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

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

- Keep this leaflet. You may need to read it again.
- Do not share ADCO-NAPACOD with any other person.
- Ask your health care provider or pharmacist 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-NAPACOD is and what it is used for.
2. What you need to know before you take ADCO-NAPACOD.
3. How to take ADCO-NAPACOD.
4. Possible side effects.
5. How to store ADCO-NAPACOD.
6. Contents of the pack and other information.

1. What ADCO-NAPACOD is and what it is used for

A: 2.8 Central nervous system depressants. Combination analgesics.

ADCO-NAPACOD is an analgesic and antipyretic used for the relief of mild to moderate pain and fever.

2. What you need to know before you take ADCO-NAPACOD

Do not take ADCO-NAPACOD:

- if you are hypersensitive (allergic) to ADCO-NAPACOD or any of the other ingredients of ADCO-NAPACOD.
- Contraindicated in respiratory depression, especially in the presence of cyanosis (a bluish discoloration of the skin due to poor circulation) and excessive bronchial secretion, after operations on the biliary tract, acute alcoholism, head injuries and conditions in which intracranial pressure (pressure exerted by fluids in the skull) is raised.
- It should not be given during an attack of bronchial asthma or in heart failure secondary to chronic lung disease.
- Patients taking monoamine oxidase inhibitors (antidepressants) or within 14 days of stopping such treatment.

Warnings and precautions

Special care should be taken with ADCO-NAPACOD:

- This product contains paracetamol and you should not take more than the recommended dose. If you have overdosed or suspect you have overdosed, contact a doctor, hospital or poison centre immediately.
- Dosages in excess of those recommended may cause severe liver damage.
- Consult your doctor if no relief is obtained with the recommended dosage.
- Do not use continuously for longer than ten days without consulting your doctor.
- Store in a safe place, out of reach of children.
- If you are suffering from liver or kidney disease you should take paracetamol under medical supervision.
- Absorption of other medicines may be delayed if administered together with ADCO-NAPACOD.
- Be cautious when taking ADCO-NAPACOD if you are suffering from hypothyroidism, Addison’s disease, impaired liver function, age-associated prostate gland enlargement or shock.

- Use ADCO-NAPACOD with caution if you suffer from inflammatory or obstructive bowel disorders.
- Reduce dose if you are an elderly or weakened.
- The depressant effects of codeine are enhanced by depressants of the central nervous system such as alcohol, anaesthetics, hypnotics and sedatives, and phenothiazines.
- Exceeding the prescribed dose, together with prolonged and continues use of this medicine, may lead to dependence and addiction.
- Not recommended for children under 6 years.

Children and adolescents

Not recommended for children under 6 years.

Other medicines and ADCO-NAPACOD

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

In particular, ADCO-NAPACOD can affect the following medicines:

- *Hepatotoxic medicines (Medicines causing damage to the liver):* Increased risk of hepatotoxicity.
- *Enzyme inducing medicines (Medicines increasing the metabolic activity of an enzyme):* increased risk of hepatotoxicity. Possible decrease in therapeutic effects of ADCO-NAPACOD.
- *Metoclopramide and domperidone (Medicine used to treat nausea and vomiting):* absorption of ADCO-NAPACOD may be increased.
- *Cholestyramine (Medicine used to lower high cholesterol levels in the blood):* absorption of ADCO-NAPACOD is reduced if given within one hour of cholestyramine.
- *Salicylates:* Prolonged use increases the risk of adverse renal effects.
- *Central nervous system depressants:* The depressant effects of codeine are enhanced.

ADCO-NAPACOD with food and drink and alcohol

The depressant effects of codeine are enhanced by alcohol.

Pregnancy and breastfeeding and fertility

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 provider for advice before taking this medicine.

Safety and/or efficacy has not been established.

Driving and using machines

Codeine has depressant effects, i.e., drowsiness and confusion which may be enhanced by nervous system depressants such as alcohol, anaesthetics, hypnotics and sedatives, and phenothiazines.

It is not always possible to predict to what extent ADCO-NAPACOD 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-NAPACOD affects them.

ADCO-NAPACOD contains:

Gelatin (200 – 220 gm);

Raspberry red powder IH 7804;

Maize starch;

Magnesium stearate.

3. How to take ADCO-NAPACOD

Always take ADCO-NAPACOD exactly as described in this leaflet or as your doctor or pharmacist or nurse has told you. Check with your doctor or pharmacist or nurse if you are not sure.

Adults: 1 to 2 tablets, repeated 6 hourly if necessary

Children 7 to 12 years: ½ to 1 tablet, repeated 6 hourly if necessary

Children under 6 years: Not recommended

- Do not exceed the recommended dose.
- Do not use continuously for longer than 10 days without consulting your doctor.

If you take more ADCO-NAPACOD than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Signs and symptoms of overdosage include:

- Nausea and vomiting;
- Narcosis;
- Feeling of exhilaration;
- Convulsions;
- Contracted pupils;
- Respiratory depression.

If you forget to take ADCO-NAPACOD

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

4. Possible side effects

ADCO-NAPACOD can have side effects.

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

If any of the following happens, stop taking / using ADCO-NAPACOD and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing;
- Rash or itching;
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to ADCO-NAPACOD. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Chest pain;
- 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 for you;
- Yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.

These are all serious side effects. You may need urgent medical attention.
Tell your doctor if you notice any of the following:

Frequent side effects:

- Drowsiness;
- Confusion;
- Restlessness;
- Nausea;
- Vomiting;
- Constipation;
- Ureteric or biliary spasm (spasm of the tube that carries urine from the kidney to the bladder).

Less frequent side effects:

- Agranulocytosis (less white blood cells in the body);
- Thrombocytopenia (abnormally low blood platelets);
- Leukopenia (lower-than-normal white blood cells in the blood);
- Pancytopenia (lower-than-normal red and white bloods cells in the blood);
- Neutropenia (deficiency of white blood cells);
- Anaemia;
- Renal colic;
- Renal failure;

- Sterile pyuria (excess presence of white blood cells in the urine);
- Hepatitis;
- Pancreatitis;
- skin rash;
- Dermatitis;

Frequency unknown:

- Pyroglutamic aciduria (5-oxoprolinuria) (metabolic condition associated with massive urinary excretion of 5-oxyproline);
- high-anion gap metabolic acidosis;
- Dry mouth;
- Vertigo;
- Bradycardia;
- Palpitations;
- Nephropathy;
- Micturition (urination);
- Urticaria;
- Pruritus;
- Sweating;
- Facial flushing;
- Hypothermia;
- Change of mood;
- Raised intracranial pressure;
- Dizziness;
- Headache;
- Miosis (excessive constriction of the pupil of the eye);
- Hypersensitivity reactions characterised by dyspnoea (shortness of breath) and orthostatic hypotension (low blood pressure).

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-NAPACOD.

5. How to store ADCO-NAPACOD

- Store all medicines out of reach of children.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).
- Store in airtight containers at or below 25 °C. Protect from light.
- KEEP OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What ADCO-NAPACOD contains

- The active substances are Codeine phosphate 10 mg and paracetamol 500 mg.
- The other ingredients are Gelatin (200 – 220 gm), raspberry red powder IH 7804, maize starch, magnesium stearate.

What ADCO-NAPACOD looks like and contents of the pack

Pink, flat, round, bevelled edge, bisected tablets measuring ½" (12,7 mm) in diameter.

Packs 100 and 500 not currently marketed.

Packs of 1 000 and 5 000.

Not all pack sizes are marketed.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

It is contained in the packaging of the medicine.