## PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

**ADCO-DOL Tablets**

**Each tablet contains:**

Codeine phosphate 10 mg

Doxylamine succinate 5 mg

Paracetamol 450 mg

Caffeine 45 mg

**Sugar free.**

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

ADCO-DOL is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use ADCO-DOL carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ADCO-DOL 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.

**What is in this leaflet:**

**1. What ADCO-DOL is and what it is used for:**

ADCO-DOL is a pain and fever combination of paracetamol with codeine phosphate. Doxylamine succinate has sedating and antihistamine properties. In combination these all treat mild to moderate pain and fever.

ADCO-DOL is used for symptomatic relief of mild to moderate pain, pain associated with tension, and fever in adults.

**2. What you need to know before you take ADCO-DOL**

Do not take ADCO-DOL:

- If you are hypersensitive (allergic) to any of the above listed ingredients of ADCO-DOL.
- If you have respiratory depression (unusual breathing), especially in the presence of cyanosis (blueish discolourisation of skin) and excessive bronchial secretion.
- After operations on the biliary tract, acute alcoholism, head injuries and conditions in which intracranial (inside skull) pressure is raised.
- It should not be given during an attack of bronchial asthma or in heart failure secondary to chronic lung disease.

**Warnings and precautions**

Special care should be taken with ADCO-DOL

• 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.

• This medicine may lead to drowsiness and impaired concentration, which is aggravated by the simultaneous intake of alcohol or other central nervous system depressant agents.

• Paracetamol dosages in excess of those recommended may cause severe liver damage.

• Exceeding the prescribed dose, together with prolonged and continuous use of this medication, may lead to dependency and addiction.

• In patients with low thyroid function, Addison's disease (low levels of cortisol and aldosterone), liver damage, enlarged prostate or shock

• It should be used with caution in patients with inflammatory or obstructive bowel disorders.

• The dosage should be reduced in elderly and debilitated patients.

• It should be used with care in patients with glaucoma and enlarged prostate.

**Use in children and adolescents**

Adults and children over 12 years: One or two tablets repeated four hourly if necessary. Do not exceed eight tablets per day.

**Other medicines and ADCO-DOL**

Always tell your healthcare professional if you are taking any other medicine.

Monoamine oxidase inhibitors or within 14 days of stopping such treatment.

The effects of atropine and tricyclic antidepressants may be enhanced..

The warning symptoms of damage caused by ototoxic drugs may be masked and the metabolism of drugs in the liver may be affected.

Doxylamine may decrease emetic response to apomorphine.

Doxylamine succinate may enhance the sedative effect of central nervous system depressants including alcohol, barbiturates, hypnotics, narcotic analgesics, sedatives and tranquillisers.

The depressant effects of codeine are enhanced by depressants of the central nervous system such as alcohol, anaesthetics, hypnotics and sedatives, and phenothiazines.

**ADCO-DOL with food and drinks.**

No known interactions with food and drink.

**Pregnancy, breastfeeding and fertility.**

Safety in pregnancy and lactation has not been established.

If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

**Driving and using machines**

Patients should be warned against driving vehicles or machinery or performing potentially hazardous tasks where loss of concentration may lead to accidents.

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

**3. How to take ADCO-DOL**

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

Always take ADCO-DOL exactly as described in this leaflet or as your doctor or pharmacist has instructed you. Check with your doctor, pharmacist or nurse if you are unsure.

**Adults and children over 12 years:**

One or two tablets repeated four hourly if necessary. Do not exceed eight tablets per day.

If you have the impression that the effect of ADCO-DOL is too strong or too weak, talk to your doctor or pharmacist.

**DO NOT EXCEED THE RECOMMENDED DOSE**

**If you take more ADCO-DOL than you should:**

Symptoms of overdosage include nausea and vomiting. Liver damage, which may be fatal, may only appear after a few days. Kidney failure has been described following acute intoxication.

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

**If you forget to take ADCO-DOL:**

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

4. **Possible side effects**

ADCO-DOL can have side effects:

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

Frequent:

- insomnia, deep sleep, drowsiness
- confusion, inability to concentrate
- incoordination, dizziness, light headedness
- headache,
- dry mouth,
- nervousness,
- tremors, convulsions
- facial flushing

Frequency not known:

- Skin rashes
- muscular weakness and twitching
- pain in lower back area, puss in the urine, difficulty passing urine
- slow pulse or palpitations (irregular heart beat)

- drop in blood pressure upon standing causing light-headedness, facial flushing and vertigo (dizzy spells)
- constipation, nausea, vomiting, diarrhea or dry mouth.

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

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

**5. How to store ADCO-DOL**

Store all medicines out of reach of children.

Store at or below 25ºC. 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-DOL 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-DOL contains

ADCO-DOL contains the following active ingredients Codeine phosphate 10 mg, Doxylamine succinate 5mg, Paracetamol 450mg and Caffeine 45mg.

### The other ingredients are:

Colour sunset FCF lake, colour quinoline yellow lake, colour quinoline yellow WS, gelatin, maize starch, magnesium stearate, purified talc, sodium starch glycolate

### What ADCO-DOL looks like and contents of the pack:

Yellow, circular, flat tablet, scored on one side only, and embossed with "ADCO" above and "DOL" below the score line.

Blister packs of 20, 40.

Securitainers of 20

### Holder of Certificate of Registration

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**Access to the corresponding professional information**

It is contained in the packaging of the medicine

Namibia: NSI 90/2.8/0083

Botswana: B9300175 S3