PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

ADCO-DOL PAIN RELIEF POWDERS, each sachet contains:

Aspirin 500 mg

Paracetamol 325 mg

Caffeine 32.5 mg

Sugar free

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

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

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

1.WHAT ADCO-DOL PAIN RELIEF POWDERS IS AND WHAT IT IS USED FOR

ADCO-DOL PAIN RELIEF POWDERS combine the analgesic and antipyretic action of aspirin and paracetamol together with the anti-inflammatory action of aspirin.

ADCO-DOL PAIN RELIEF POWDERS is used for the relief of mild to moderate pain and fever.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ADCO-DOL PAIN RELIEF POWDERS.

Do not take ADCO-DOL PAIN RELIEF POWDERS

- If you are allergic to aspirin, paracetamol, caffeine or any of the other ingredients of ADCO-DOL PAIN RELIEF POWDERS (listed in section 6.1).
- If you are suffering from renal diseases
- If you have chronic gastritis.
- If you have peptic ulcers and dyspepsia
- If you have haemophilia or on an oral anticoagulant.
- If you have heart failure
- If you have history of gastrointestinal perforation (small holes in the stomach), ulceration or bleeding (PUBs) related to previous NSAIDs, including ADCO-DOL PAIN RELIEF POWDERS.
- If you have active or history of recurrent ulcer/haemorrhage/perforations.
- If you are pregnant, do not use ADCO-DOL PAIN RELIEF POWDERS at 20 weeks or later in your pregnancy unless specifically advised to do so by your health care professional because these medicines may cause problems in your unborn baby**.**
- If you are younger than 16 years old.

Warnings and precautions

Special care should be taken with ADCO-DOL PAIN RELIEF POWDERS

- Tell your doctor or health care provider if you are pregnant or plan to become pregnant. Taking NSAIDs at about 20 weeks of pregnancy or later may harm your unborn baby. If you need to take NSAIDs for more than 2 days when you are

between 20 and 30 weeks of pregnancy, your healthcare provider may need to monitor the amount of fluid in your womb around your baby. You should not take NSAIDs after about 30 weeks of pregnancy.

- has been implicated in Reye's Syndrome, a rare but serious illness in children and teenagers, with chicken pox and influenza.
- It should be administered with caution to patients with impaired renal function, dyspepsia, anaemia and when the patient is dehydrated.
- Caution is required in patients with a history of hypertension and/or heart failure as fluid retention and oedema have been reported in association with ADCO-DOL PAIN RELIEF POWDERS therapy. In view of the ADCO-DOL PAIN RELIEF POWDERS inherent potential to cause fluid retention, heart failure may be precipitated in some compromised patients.
- Caution is required in patients with significant risk factors for cardiovascular events (e.g., hypertension, hyperlipidaemia, diabetes mellitus, smoking) and should only be treated with diclofenac after careful consideration.
- Elderly: The elderly have an increased frequency of adverse reactions to NSAIDs including ADCO-DOL PAIN RELIEF POWDERS, especially gastrointestinal perforation, ulceration and bleeding (PUBs) which may be fatal.
- The risk of gastrointestinal perforation, ulceration or bleeding (PUBs) is higher with increasing doses of ADCO-DOL PAIN RELIEF POWDERS, in patients with a history of ulcers, and the elderly.
- When gastrointestinal bleeding or ulceration occurs in patients receiving ADCO-DOL PAIN RELIEF POWDERS, treatment with ADCO-DOL PAIN RELIEF POWDERS should be stopped.
- ADCO-DOL PAIN RELIEF POWDERS should be given with caution to patients with a history of gastrointestinal disease (e.g. ulcerative colitis, Crohn's disease, hiatus

hernia, gastro- oesophageal reflux disease, angiodysplasia) as the condition may worsen.

- Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis have been reported. ADCO-DOL PAIN RELIEF POWDERS should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.

- Dosages in excess of those recommended may cause severe liver damage.
- Patients suffering from liver or kidney disease should take paracetamol under medical supervision.
- Do not use continuously for more than ten days without consulting your doctor.
- Consult your doctor if no relief is obtained with the recommended dosage.

Use in children and adolescents

Do not give ADCO-DOL PAIN RELIEF POWDERS to children under the age of 16 years.

Other medicines and ADCO-DOL PAIN RELIEF POWDERSS

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

Aspirin may enhance the activities of oral anti-diabetic preparations and sulphonamides. Aspirin diminishes the effects of anti-gout preparations such as probenecid and sulphinpyrazone.

Barbiturates and other sedatives may mask the respiratory symptoms of aspirin overdosage and have been reported to enhance its toxicity

NSAIDs: use of two or more NSAIDs concomitantly could result in an increase in side effects

Corticosteroids: increased risk of gastrointestinal perforation, ulceration or bleeding (PUBs)

Anti-coagulants: ADCO-DOL PAIN RELIEF POWDERS may enhance the effects of anti-coagulants such as warfarin

Anti-platelet medicines and selective serotonin reuptake inhibitors (SSRIs): increased risk of gastrointestinal bleeding.

ADCO-DOL PAIN RELIEF POWDERS with food and drink

No known interactions with food and drink.

Pregnancy and breast-feeding

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.

Driving and using machines

The effect on ability driving and using of machines has not been established.

3.HOW TO TAKE ADCO-DOL PAIN RELIEF POWDERS

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

Always take ADCO-DOL PAIN RELIEF POWDERS exactly as described in this leaflet or as your doctor or pharmacist have told you.

Check with your doctor or pharmacist if you are not sure.

Adults and children over 16 years old:

One sachet of powder to be taken with water every six hours as needed. For best results take the powder dry on the tongue followed by a glass of water.

Do not exceed four (4) doses per 24 hours.

Not to be taken by children under the age of 16 years.

Use the lowest effective dose for the shortest possible duration of treatment.

DO NOT EXCEED THE RECOMMENDED DOSE.

If you take more ADCO-DOL PAIN RELIEF POWDERS than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison center. Treatment is supportive and symptomatic. Specialised treatment is essential as soon as possible.

The most likely symptoms of overdosage are dizziness, ringing sound in the ear, sweating, nausea, vomiting, mental confusion, hyperventilation, respiratory alkalosis, metabolic acidosis, ketosis restlessness, excitement, muscle tremor, impaired vision, tachycardia, pallor, abdominal pains, anorexia extrasystoles and depression of the central nervous system.

In children serious signs of overdosage may develop rapidly.

Liver damage which may be fatal, may only appear after few days. Kidney damage has been described following acute intoxication.

If you forget to take ADCO-DOL PAIN RELIEF POWDERS

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

4.POSSIBLE SIDE EFFECTS

ADCO-DOL PAIN RELIEF POWDERS can have side effects:

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

Side effects includes:

-Anaemia, blood disorders, swelling, hypertension, cardiac failure,

-peptic ulcers, gastrointestinal bleeding, nausea, vomiting, diarrhoea, flatulence, constipation, dyspepsia, abdominal pain, black stools, vomiting blood, worsening of colitis and Crohn's disease, gastritis, dizziness, renal papillary necrosis, Liver disease, kidney disease, reversible skin rash, headache and insomnia.

-Hypersensitivity reactions which may include skin eruptions, paroxysmal bronchospasm and dyspnoea.

-Bullous reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. 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 PAIN RELIEF POWDERS

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

Adcock.AEReports@adcock.com

5. HOW TO STORE

Store all medicine out of reach of children.

Store at or below 25 ºC.

Protect from moisture.

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

Return all unused medicine to your pharmacist.

Do not dispose of unused medicines in drain or sewerage system (e.g. toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What it contains:

ADCO-DOL PAIN RELIEF POWDERS contains the active ingredient aspirin, paracetamol and caffeine.

The other ingredients are:

Colloidal Silicon Dioxide, Hexacol Red 2 G Lake, Sodium Cyclamate, Sodium Lauryl Sulphate, Sunset Yellow FCF Supra, Sunset Yellow FCF Lake.

What ADCO-DOL PAIN RELIEF POWDERS looks like and contents of the pack:

Fine, homogenous, orange powder.

Holder of Certificate of Registration

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand, 1685

Private Bag X69

Bryanston, 2021

0860ADCOCK (232625)

This leaflet was revised in

N/A new leaflet (Approved on 30 November 2021)

Registration Number

R/2.9/238

Access to the corresponding professional information

It is contained in the packaging of the medicine