SCHEDULING STATUS

S2

CODPARAFEN, **10 mg/200 mg/250 mg, capsules**

Codeine phosphate, ibuprofen, paracetamol

Sugar free

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

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

Nevertheless, you still need to use CODPARAFEN carefully to get the best results from it.

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

What is in this leaflet

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

Date of approval: 14 June 2023

1. What CODPARAFEN is and what it is used for

This medicine contains Codeine. Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain.

This medicine also contains Ibuprofen. Ibuprofen, a non-steroidal anti-inflammatory medicine (NSAID), also acts to reduce swelling (inflammation).

This medicine also contains paracetamol. Paracetamol, an analgesic, acts to relieve pain.

This medicine can be used for the short-term treatment of mild to moderate pain (with or without fever).

2. What you need to know before you take CODPARAFEN

Do not take CODPARAFEN

- If you are hypersensitive (allergic) to codeine, ibuprofen or paracetamol or any of the other ingredients of CODPARAFEN (listed in section 6).
- If you have liver or kidney problems.
- If you have heart failure.
- If you have had a bleeding stomach ulcer after taking a non-steroidal anti-inflammatory medicine (NSAID) (you may have been sick and it contained blood or dark particles that look like coffee grounds, passed blood in your stools or passed black tarry stools).
- If you have a stomach ulcer, perforation or bleeding from the ulcer, or have had an ulcer in the past.
- If you have had a condition called cardiovascular disease (you may have had chest pain, or tightness, or discomfort, shortness of breath; or pain, numbness, weakness or coldness in your legs or arms if the blood vessels in those parts of your body are narrowed; or you might have had a blood clot).

- If you have difficulty breathing or breathing problems.
- If you have had an operation on the biliary tract.
- If you regularly drink large quantities of alcohol.
- If you have seizures or have had head injuries.
- If you are taking medicines to treat depression or bipolar disorder called monoamine oxidase inhibitors or have stopped taking these medicines within the last 14 days.
- If you have asthma, urticaria (itchy, raised, red or skin-coloured swellings) or allergic-type reactions after taking aspirin, or other NSAIDs.
- If you are pregnant, do not use NSAIDs, including CODPARAFEN 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.

Warnings and precautions

Note that the safety of continuous use of CODPARAFEN for more than four weeks has not been proven, and is therefore seen as unsafe to use it for longer than four weeks.

Take special care with CODPARAFEN:

Codeine

- If you use more than what you should or for longer periods, it can cause dependence and addiction to CODPARAFEN.
- If you have any of the following conditions, as CODPARAFEN can make the symptoms of these conditions worse:
    - hypothyroidism (you may have experience tiredness, being sensitive to cold, weight gain, constipation, depression, muscle aches and weakness, muscle cramps),

- adrenocortical insufficiency (you may have experienced upper body obesity, round face and neck, and thinning arms and legs, skin problems, such as acne or reddish-blue streaks on the abdomen or underarm area, high blood pressure, muscle and bone weakness, moodiness, irritability, or depression, high blood sugars),
- asthma,
- an enlargement of your prostate gland,
- low blood pressure,
- bowel problems including blockage of your bowel,
- myasthenia gravis (a disorder that causes weakness in the skeletal muscles, which are the muscles your body uses for movement).

- If you are elderly or weak and feeble. You should take a lower dose as it is more likely that you might have side effects.

Ibuprofen

- If you have high blood pressure or heart failure as CODPARAFEN may cause water retention, which can result in heart failure.
- If you are elderly, as you have an increased frequency of adverse reactions to NSAIDs including CODPARAFEN, especially sores on the inside lining of your stomach and intestine and bleeding that can be fatal.
- If you have had a bleeding ulcer as the risk of this to start again is high with increasing doses of CODPARAFEN. When gastrointestinal bleeding or ulceration occurs in patients receiving CODPARAFEN, stop taking CODPARAFEN and go to your doctor, pharmacist or other health care provider.
- If you have had gastrointestinal disease (e.g. ulcerative colitis, (inflammation and sores in your digestive tract), Crohn's disease (inflammation of your digestive track), hiatus hernia (stomach

pushing through an opening in the diaphragm), gastroesophageal reflux disease (stomach acid flows back into the tube connecting your mouth and stomach)), as CODPARAFEN can cause these conditions to worsen.

- If you have a serious skin reactions, including peeling and blistering of the skin. The peeling may progress quickly, resulting in large raw areas that may ooze or weep (e.g. Stevens-Johnson syndrome). Stop taking CODPARAFEN at the first appearance of skin rash, or any other sign of hypersensitivity and go to your doctor or nearest hospital.
- If you are in the last three months of pregnancy. CODPARAFEN may delay in onset of labour and may increase the duration thereof.
- If you have an infection, as CODPARAFEN can hide symptoms such as fever and inflammation, which can result in not treating the inflammation effectively.
- If you have a bleeding disorder, as CODPARAFEN can worsen this condition (see 'Other medicines and CODPARAFEN').
- Tell your doctor or health care provider if you are pregnant or plan to become pregnant. Taking NSAIDs at around 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 your pregnancy, your healthcare provider may need to monitor the amount of fluid in your womb around your baby. You should not take NSAIDs around 30 weeks of pregnancy or later.
- If you develop a fever, skin rash, swelling of the lymph nodes and/or swelling of the face. This is known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). Stop taking CODPARAFEN and go to your doctor or nearest hospital, as this can be life threatening.

Paracetamol

- CODPARAFEN contains paracetamol which may be fatal if you take a higher dose than you should. In the event of overdosage or if you suspect that you have taken more than you should,

even if you do not have any symptoms of an overdose, go to your nearest doctor, hospital or Poison Centre must immediately.

- If you take more paracetamol as in CODPARAFEN, you may cause your liver to be severely damaged.

Children and adolescents

Do not give CODPARAFEN to children under the ages of 12 years.

Other medicines and CODPARAFEN

Always tell your health care provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

Codeine

- Medicines for anxiety and sleeping pills, e.g. temazepam, pentobarbital and phenothiazines and alcohol as CODPARAFEN may make the effect of these medicines stronger.

Ibuprofen

- Lithium (to treat mood disorder), methotrexate (to treat certain types of cancer and arthritis) and cardiac glycosides (for your heart e.g. digoxin and digitoxin), as CODPARAFEN can increase the concentrations of these medicines.
- ACE inhibitors (to lower blood pressure, e.g. captopril, enalapril, lisinopril to name a few), cyclosporin and tacrolimus (usually used after an organ transplant), or diuretics (water pills, e.g. furosemide, hydrochlorothiazide and spironolactone to name a few) as CODPARAFEN together with these medicines can increase your risk to damage your kidneys.

- Medicines for high blood pressure (e.g. ACE inhibitors, beta blockers (e.g. atenolol, metoprolol, propranolol to name a few) and diuretics. CODPARAFEN has may increase the concentrations of these medicines.
- Quinolones (a type of antibiotic used to treat infections) and your might have convulsions.
- Moclobemide (used to treat depression and anxiety) as you might experience more side effects from ibuprofen as in CODPARAFEN.
- Phenytoin (used to treat epilepsy) and sulphonylurea (to treat diabetes) as the effects of these medicines may become stronger.
- Mifepristone (a medicine used in abortions): CODPARAFEN should not be used for 8 to 12 days after you have used mifepristone as ibuprofen can reduce the effect of mifepristone.
- Zidovudine (to treat HIV/AIDS) as using it with CODPARAFEN may increase your risk to damage your red blood cells.
- NSAIDs and the use of two or more NSAIDs together with CODPARAFEN could result in you having more side effects.
- Alcohol, bisphosphonates (used to prevent or treat bone loss, e.g. alendronate, etidronate, risedronate and zoledronic acid) or oxpentifylline (to treat muscle pain) as CODPARAFEN together with these medicines can increase your risk to have peptic ulcers.
- Corticosteroids (medicines that lower inflammation in your body) as CODPARAFEN together with these medicines can increase your risk to have peptic ulcers and bleeding.
- Anti-coagulants (medicines that help to prevent blood clots, e.g. apixaban, dabigatran, edoxaban, rivaroxaban, warfarin. CODPARAFEN may make the effects of these medicines stronger.
- Anti-platelet medicines (e.g., clopidogrel, ticagrelor, prasugrel dipyridamole or aspirin to name a few) and selective serotonin reuptake inhibitors (SSRIs) (used to treat depression, e.g.,

escitalopram, fluoxetine, paroxetine to name a few) as it might increase your risk of gastrointestinal bleeding.

CODPARAFEN with food, drink and alcohol

Do not drink alcohol (wine, beer, spirits) whilst taking this medicine. Alcohol may make you feel drowsier, increase your risk of having a peptic ulcer and bleeding, and increase your risk of liver damage.

Pregnancy, 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 CODPARAFEN.

Use of NSAIDs (as in CODPARAFEN) during the third trimester of pregnancy may result in breathing problems of your new-born child (see section 2,'Do not take CODPARAFEN' and 'Warnings and precautions').

Fertility

No data on male and female fertility are available

Driving and using machines

It is not always possible to predict to what extent CODPARAFEN may interfere with your daily activities. CODPARAFEN may make you feel dizzy or sleepy. You should ensure that you do not engage in activities requiring mental alertness, judgment and/or sound coordination and vision e.g. driving, riding, flying, sailing or operating machines/equipment until you are aware of the measure to which CODPARAFEN affects you.

3. How to take CODPARAFEN

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

Always take CODPARAFEN exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

DO NOT EXCEED THE RECOMMENDED DOSE.

The usual dose for adults and children over the age of 12 years is:

One to two capsules four to six hourly and not more than six capsules per twenty-four hours.

Start with the lowest effective dose for the shortest possible time. Swallow each capsule with water.

Talk to your doctor if you do not feel better with the recommended dosage after three days.

If you take more CODPARAFEN than you should

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

Prompt medical attention is critical. Even if you do not show symptoms of an overdose, go immediately to your nearest hospital or Poison Centre.

CODPARAFEN contains paracetamol and an overdose, can be fatal.

The symptoms of an overdose can include nausea, stomach pain, loss of appetite, vomiting (may be blood streaked), ringing in the ears, excitement, convulsions (mainly in children), and breathing problems.

If you forget to take CODPARAFEN

It is important to take CODPARAFEN as your doctor has prescribed. If you miss a dose, resume your usual schedule the following day. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

CODPARAFEN can have side effects.

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

If any of the following happens, stop taking CODPARAFEN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Rashes, including peeling and blistering of the skin. The peeling may progress quickly, resulting in large raw areas that may ooze or weep (e.g. Stevens-Johnson syndrome).
- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Bronchospasm (difficult to breath and cause wheezing).
- Liver damage (dark coloured urine, light coloured bowel movements, yellow skin and eyes and loss of appetite).
- Aseptic meningitis (serous inflammation of the linings of the brain with headache and fever).
- Fever, skin rash, swelling of the lymph nodes and/or swelling of the face (also known as DRESS) (see section 2, ‘Warnings and precautions’),

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

Codeine

Side effects of unknown frequency

- Mood changes, hallucinations,
- Drowsiness, dizziness, headache, confusion, feeling restless, feeling dizzy (vertigo),
- Small pupils (miosis),
- Irregular heartbeat,
- A sudden drop in blood pressure when you stand up (orthostatic hypotension),
- Nausea, vomiting, constipation, dry mouth.
- Sweating, facial flushing, hives (urticaria), itching,
- Difficult or painful urinating,
- Low sex drive,
- Low body temperature.

Ibuprofen

Frequent side effects

- Hypersensitivity (e.g. fever, swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing)
- Dizziness
- Nausea and pain in the abdomen

Less frequent side effects

- Low blood cells, may cause tiredness, easy bruising, frequent nose bleeds and increased risk of infections,
- Nervousness, depression, drowsiness, sleeplessness (insomnia),
- Change in your vision,

- Ringing in your ears (tinnitus),
- Oedema, hypertension, heart failure,
- Vomiting, diarrhoea, wind (flatulence), constipation, indigestion, peptic ulcers, bleeding from the ulcers, dark sticky stools, vomiting of blood, pain in the abdomen,
- Blistering of the skin, severe skin reaction can occur including Stevens-Johnson syndrome and toxic epidermal necrolysis. Symptoms includes skin rash, blistering and peeling of the skin,
- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) (for details on this condition, please refer to serious side effects above and section 2, 'Warnings and precautions'),
- Kidney failure.

Side effects of unknown frequency

- Changes in the way your blood clots,
- Fever,
- Headache and vertigo,
- Worsening of colitis and Chron's disease, and gastrointestinal discomfort.
- Kidney disorders (blood in the urine, fever, changed in urinating, nausea and vomiting, swelling)

Paracetamol

Less frequent side effects

- Low blood cells, may cause tiredness, easy bruising, frequent nose bleeds and increased risk of infections
- Hypersensitivity reactions
- Skin rashes. The rash is usually reds or itchy but sometimes more serious and accompanied by fever and, swelling and ulcers in the mouth

Side effects of unknown frequency

Pancreatitis (you may experience abdominal pain that radiates to your back, or abdominal pain that feels worse after eating, fever, tenderness when touching the abdomen)

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. This includes any possible side effects not listed in this leaflet. 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 CODPARAFEN.

5. How to store CODPARAFEN

Store all medicines out of reach of children.

- Store at or below 25 °C in well-closed containers.
- Do not use after the expiry date stated on the label/carton/blister.
- 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 CODPARAFEN contains

The active substances are codeine phosphate 10 mg, ibuprofen 200 mg and paracetamol 250 mg.

The other ingredients are colloidal silica, magnesium stearate, maize starch, potassium sorbate, hard gelatin capsule (capsule shell: opaque green cap, opaque red body), printing ink.

Capsule shell colourants are Brilliant blue FCF (E133, C.I. 42090), Erythrosine (E127, C.I. 45430), Quinoline yellow (E104, C.I. 47005), Sunset yellow (E110, C.I. 15985) and Titanium dioxide (E171, C.I. 77891).

What CODPARAFEN looks like and contents of the pack

The cap is opaque green, and the body is opaque red. “ADCO” is printed on both the cap and body. Contents of the capsule are fine white granular powder.

Content of the packaging

- A white high-density polypropylene (HDPP) securitainer with a low-density polyethylene (LDPE) snap on lid or a white high density polyethylene container with a high density polyethylene (HDPE) screw cap containing 30 capsules.
- Push through clear PVC and aluminium blister packs of 10 capsules in unit cartons of 10, 30, 60 or 100 capsules.

Holder of Certificate of Registration

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