SCHEDULING STATUS

S2

CODOXOL tablets

Codeine phosphate, doxylamine succinate, paracetamol, caffeine Sugar free

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

- CODOXOL is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use CODOXOL carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share CODOXOL 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 3 days.

What is in the leaflet

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

1. What CODOXOL is and what it is used for

CODOXOL contains caffeine, codeine phosphate, doxylamine succinate and paracetamol. Paracetamol acts as an analgesic (painkiller) and an antipyretic (lowers body temperature), codeine phosphate is an analgesic, doxylamine succinate is an antihistamine and caffeine is a mild stimulant.

CODOXOL is indicated for short-term treatment of pain associated with tension.

2. What you need to know before you take CODOXOL

Do not take CODOXOL

- if you are allergic to paracetamol, doxylamine succinate, codeine phosphate or caffeine, or any of the other ingredients of CODOXOL (listed in section 6).
- if you are taking a medicine of the class known as Monoamine Oxidase Inhibitors (MAOIs, e.g. selegiline, moclobemide), which are used as antidepressants, or if you had taken any medicine of this group in the past 14 days.
- if you are taking other medicines containing codeine or any other paracetamol-containing medicines.
- if you have kidney or liver problems.
- if you have been told by your doctor that you have a metabolic disorder called acute intermittent porphyria. Signs include severe abdominal pain, constipation or diarrhea, nausea and vomiting, and pain in your chest, legs or back.
- if you have recently had an operation on your bile duct (biliary tract).
- if you are an alcoholic.
- if you have had a head injury or been told by your doctor that you have increased pressure in your head. Signs of this include headaches, being sick (vomiting) and blurred eyesight.
- if you are having an asthma attack or have severe breathing problems.
- if you are pregnant or breastfeeding your baby.

- if you have been told by your doctor that your body metabolises codeine to morphine very quickly.
- if you have a personal or family history of substance abuse or mental health disorders, then there is an increased risk of addiction.

Warnings and precautions

Take special care:

- if you have high blood pressure or any heart problems.
- if you have thyroid or hormonal problems.
- if you have an enlarged prostrate.
- if you have trouble to pass urine.
- if you have pressure in the eyes.
- if you are in shock, or if you have a history of drug abuse or are emotionally not stable.
- if you have any bowel or abdominal problems (e.g. stomach ulcer).
- if you have had a recent operation on the gastrointestinal tract.
- if you have gall stones.
- if you have a condition known as myasthenia gravis which weakens the muscles.
- if you suffer from seizures.
- if you are elderly.
- if you suffer from life threatening skin reactions such as Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN).
- if you develop a red, scaly widespread rash with bumps under the skin and/or blisters mainly localized on the skin folds, trunk, and upper extremities accompanied by fever at the start of treatment (acute generalized exanthematous pustulosis).
- if you develop a skin rash, swelling of lymph nodes and increase of eosinophils (a type of white blood cells). This is known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).

- if you develop or have a history of Fixed Drug Eruptions (FDE) (may look like round or oval patches and swelling of the skin), blistering (hives), itching.

Other medicines and CODOXOL

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

Tell your doctor or pharmacist if you are taking or have recently taken any of the following medicines:

- Metoclopramide, domperidone used to treat nausea and vomiting.
- Medicines used to thin the blood such as warfarin (or other coumarins).
- Medicines which make you drowsy or sleepy (CNS depressants) (e.g. barbiturates, anaesthetics, hypnotics, other opioid analgesics, anxiolytic sedatives, antipsychotics, tricyclic antidepressants and phenothiazines) or a benzodiazepine used to treat anxiety or sleep disorders.
- Medicines for the treatment of high blood pressure (diuretics and antihypertensives).
- Medicines to treat or prevent clinical depression (antidepressants).
- Medicines used to treat mental distress or disorder (antipsychotics).
- Any of the group called antimuscarinics (e.g. atropine, hyoscine).
- Any of the group called neuromuscular blockers (e.g. tubocurarine).
- Cholestyramine used for lowering blood cholesterol levels.
- Hydroxyzine used to treat anxiety and tension.
- Mexiletine used to treat irregular heartbeat.
- Kaolin or loperamide used for the treatment of diarrhoea.
- Naloxone used to treat a narcotic overdose.
- Naltrexone used as part of a treatment program for drug or alcohol dependence.
- Cimetidine used to treat stomach ulcers.
- Cisapride used to treat gastro-oesophageal reflux disease.

- Quinidine used to treat irregular heart rate.

CODOXOL with food and drink

CODOXOL should not be taken with alcohol.

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 healthcare provider for advice before taking CODOXOL.

Driving and using machines

CODOXOL may cause drowsiness and impair your concentration. If you experience these side effects, do not drive or operate machinery.

3. HOW TO TAKE CODOXOL

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

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

The usual dose is:

Adults and children 12 years and older:

2 tablets every 4 hours as needed. Do not exceed 8 tablets per day.

If you take more CODOXOL than you should

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

If you forget to take CODOXOL

If you forget to take a dose, take it as soon as you remember. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

CODOXOL can have side effects.

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

If any of the following happens, stop taking/giving CODOXOL 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 CODOXOL. 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:

- low number of white blood cells. Signs include: fever, chills, sore throat,
- low number of cells involved with blood clotting. Signs include: more or worse bruises than normal, small purple or red dots under your skin, nosebleeds or bleeding gums, black or bloody-looking bowel movements, red or pink urine,

- an excessive breakdown of red blood cells causing a type of anaemia. Signs include: tiredness, headaches, shortness of breath, dizziness, looking pale and yellowing of the skin and the whites of the eyes,
- low number of red blood cells, white blood cells and cells involved with blood clotting. Signs include: weakness, tiredness, skin problems such as rashes or bruising, rapid heart rate, shortness of breath,
- changes in mood, anxiety, feeling depressed, confusion,
- perceptions of having seen, heard, touched, tasted or smelled something that wasn't actually there,
- seizures,
- slowing down of the central nervous system. Signs include: slower heart rate and breathing, extreme confusion and memory loss and poor judgement,
- increased pressure in the head. Signs include headache, blurred vision, feeling less alert than usual and vomiting,
- blurred vision, constriction of the pupil of the eye,
- ringing in the ears,
- changes in the way your heart beats, drop in blood pressure when standing up making (causing light-headedness or fainting),
- yellowing of the skin, whites of the eyes and mucous membranes (jaundice),
- difficulty in urinating, inability to empty all the urine from your bladder,
- sudden drop in body temperature,
- skin rash or itching, which may include redness, hives (red itchy bumps), blisters, pustules or peeling of the skin (Toxic Epidermal Necrolysis) and bleeding in the lips, eyes, mouth, nose and genitals (Toxic Epidermal Necrolysis or Stevens-Johnson Syndrome),
- a red, scaly, widespread rash with bumps under the skin and blisters mainly localized on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (Acute Generalised Exanthematous Pustulosis),

- a severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells),
- Fixed Drug Eruptions (FDE) (may look like round or oval patches of redness and swelling of the skin), blistering (hives), itching.

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,
- nausea, vomiting, constipation

Less frequent side effects:

- severe stomach pain, which may reach to your back. This could be a sign of inflammation of the pancreas (pancreatitis).

Side effects with unknown frequency:

- dry mouth, sores in the mouth
- changes in the way you move, talk or do regular activities,
- sleep disturbances,
- restlessness,
- decreased libido,
- lack of energy,
- dizziness,
- incoordination,

- headache,
- sensitivity to light,
- tingling or prickling, “pins-and-needles” sensation in the arms, hands, legs or feet,
- involuntary shaking of the hands, legs, face, head or vocal cords,
- thick phlegm,
- heartburn, diarrhoea, stomach pain,
- painful muscles,
- fever, sweating,
- hair loss,
- reddening of the face.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

Reporting suspected adverse reactions after authorisation of PATRAM is important. It allows continued monitoring of the benefit/risk balance of PATRAM. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the “6.04 Adverse Drug Reactions Reporting Form”, found online under SAHPRA’s publications: Suspected adverse reactions can also be reported directly to the HCR via email: pharmacovigilance.africasme@sunpharma.com or Tel: +27(0) 12 643 2000. By reporting side effects, you can help provide more information on the safety of CODOXOL.

5. How to store CODOXOL

- Store all medicines out of reach of children.
- Store at or below 25 °C, in a dry place.
- Protect from light. Keep containers well closed.
- Do not store in a bathroom.

- Do not use after the expiry date stated on the label or bottle.
- 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 CODOXOL contains

The active substances are codeine phosphate, doxylamine succinate, paracetamol and caffeine.

Each tablet contains 10 mg of codeine phosphate, 5 mg of doxylamine succinate, 450 mg of paracetamol and 30 mg of caffeine.

The other ingredients are:

Colloidal silicone dioxide, magnesium stearate, povidone, quinolene yellow H8573 (C.I. 47005), sodium starch glycolate, starch maize, talc.

What CODOXOL looks like and contents of the pack

Round, yellow flat tablet scored on one side.

Blister packs of 10 tablets per blister strip.

20, 40 and 100 tablets in a securitainer and 1000 tablets in a white HDPE bottle.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

To follow