PACKAGE LEAFLET: Information for the patient

Co-DOLOR

Tablets –500 mg / 30 mg

(Paracetamol / Codeine phosphate hemihydrate)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further question, ask your doctor or pharmacist.
- This medication has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. WHAT CO-DOLOR IS AND WHAT IT IS USED FOR

Co-DOLOR contains a combination of the active substances paracetamol and codeine phosphate hemihydrate, a combination of the group of drugs called analgesics, which act as painkillers. Paracetamol acts also as an antipyretic (lowers high temperature), while codeine belongs to a group of drugs called opioid analgesics which relieve pain.

Co-DOLOR is used for the short - term treatment of acute moderate or severe pain that is not relieved by other analgesics such as ibuprofen or paracetamol used alone.

This codeine-containing medicine is indicated in adults and children aged 12 years and over.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CO-DOLOR

Do not take Co-DOLOR:

- if you are hypersensitive to paracetamol, codeine phosphate hemihydrate or to any of the excipients of Co-DOLOR;
- if you have acute respiratory depression and obstructive airways disease;
- in acute attacks of asthma;
- if you have acute alcoholism, head injuries, and conditions in which intracranial pressure is raised;
- if you are in coma;
- if you are known to be codeine ultra-rapid metabolisers, as the risk of morphine intoxication is extremely high;
- if you have severe liver disease;
- if you are under 12 years of age;
- if you are a child with breathing problems;
- for the treatment of pain in patients under 18 years who undergo tonsillectomy and/or adenoidectomy for Obstructive Sleep Apnoea Syndrome due to an increased risk of developing serious and life-threatening adverse reactions;
- if you are at the end of pregnancy; about to give birth;
- if you are at risk for preterm delivery;
- if you are breastfeeding.

Take special care with Co-DOLOR

Talk to your doctor or pharmacist before taking Co-DOLOR.

Regular, prolonged use of Co-DOLOR, may lead to addiction and tolerance.

Co-DOLOR should be used with caution:

- in patients with renal impairment;
- in patients with hepatic impairment;
- in patients with impaired respiratory function (avoid in chronic obstructive pulmonary disease) and asthma;
- in patients with hypotension, shock;
- in patients with myasthenia gravis;

- in patients with convulsive disorders;
- in patients with prostatic hypertrophy;
- in patients with obstructive or inflammatory bowel disorders (colitis or Crohn's disease);
- in patients with diseases of the biliary tract;
- in patients with a history of drug dependency;
- if you have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating when you have stopped taking alcohol or drugs;
- if you are taking benzodiazepines;
- if you have an underactive thyroid gland;
- if you have problems with your adrenal glands (Addison's disease);
- because taking analgesics too often, especially combination of analgesics, may cause prolonged damage of the kidneys (nephropathy from analgesics);

During treatment with Co-DOLOR , tell your doctor straight away if:

You have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

To avoid the possibility of overdosage you should make sure not to take at the same time other drugs that contain paracetamol or codeine.

Taking a painkiller for headaches too often or for too long can make them worse.

A reduced dose is recommended in elderly or debilitated patients, in hypothyroidism, and in adrenocortical insufficiency.

If the first signs of a hypersensitivity reaction appear after taking Co-DOLOR, the therapy should be discontinued immediately.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Drugs that can interact with paracetamol and codeine are:

Alcohol: enhanced hypotensive and sedative effects when opioid analgesics given with alcohol.

Antiemetics: metoclopramide increases the rate of absorption of paracetamol and raises its maximum plasma levels. Similarly, domperidone may increase the rate of absorption of paracetamol.

Opioid analgesics antagonise the effects of metoclopramide and domperidone on gastro-intestinal activity.

Antiepileptics: the metabolism of paracetamol is increased in patients taking enzyme-inducing antiepileptics (carbamazepine, phenytoin, phenobarbital, primidone).

Anticoagulants: prolonged regular use of paracetamol possibly enhances anticoagulant effect of coumarins (warfarin).

Antipsychotics: enhanced hypotensive and sedative effects when opioid analgesics are given with antipsychotics.

Antihistamines: sedative effects possibly increased when opioid analgesics given with sedating antihistamines.

Antidepressants: sedative effects possibly increased when opioid analgesics given with tricyclics. CNS excitation or depression (hypertension or hypotension) may occur when opioid analgesics are given with MAO inhibitors.

Chloramphenicol: an antibiotic.

Flucloxacillin: flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

Lipid-regulating drugs: absorption of paracetamol is reduced by colestyramine.

Probenecid reduces the clearance of paracetamol.

Sedatives: paracetamol reduces the urinary excretion of diazepam but diazepam plasma levels are little affected.

Patients should not take any other paracetamol containing medicines whilst taking Co-DOLOR.

CNS effects of opioid analgesics are possibly increased by barbiturates.
In general, the concurrent use of opioids and benzodiazepines results in both beneficial analgesic effects, and enhanced sedation and respiratory depression; however, in some cases benzodiazepines have antagonised the respiratory depressant effects of opioids, and, rarely, have antagonised their analgesic effects.

Taking Co-DOLOR with food and drinks
Do not drink alcohol while being treated with Co-DOLOR because the hypotensive and sedative effect is enhanced and the risk for side effects is raised.

Pregnancy and breastfeeding
Pregnancy
If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medication since the use of this drug may cause problems for the child.
Do not take Co-DOLOR if you are at the end of pregnancy, about to give birth or if you are at risk for preterm delivery.
Paracetamol and codeine cross the placenta.
Respiratory depression and withdrawal symptoms can occur in the neonate if opioid analgesics are used during delivery, also gastric stasis and inhalation pneumonia has been reported in the mother if opioid analgesics are used during labour.
Ask your doctor for advice before taking any medicinal product.

Breastfeeding
If you are breastfeeding, ask your doctor or pharmacist for advice before taking this medication.
Co-DOLOR should not be used during breast-feeding because paracetamol and codeine are distributed into breast milk. Breastfed infants of mothers taking codeine may be at an increased risk of toxicity from its metabolite, morphine.

Driving and using machines

Codeine may cause dizziness and drowsiness which affect the ability to perform skilled tasks. Those so affected should not drive or operate machinery.

3. HOW TO TAKE CO-DOLOR

Always take Co-DOLOR exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Co-DOLOR should be used at the lowest effective dose for the shortest period of time.

The usual doses are described below:

Adults and children over 12 years old: 1–2 tablets, if necessary up to 4 times a day. The interval between two doses should not be shorter than 6 hours. Maximum 8 tablets per day, the maximum daily dose should not be exceeded in any case.

The daily dose of codeine should not exceed 240 mg.

Duration of treatment: for both adults and children, the duration of treatment should be limited to 3 days.

Children under 12 years: not recommended.

Administration in hepatic or renal impairment.

The dosage of Co-DOLOR should be reduced according to hepatic or renal function in patients with hepatic or renal impairment.

If you take more Co-DOLOR than you should

Do not take more Co-DOLOR than the dose you have been recommended.

Paracetamol overdosage can result in severe liver damage and sometimes acute renal tubular necrosis.

After high doses of codeine, muscle rigidity, rhabdomyolysis, excitement and convulsions may occur. Death may occur from respiratory failure.

If you forget to take Co-DOLOR

If you forget to take Co-DOLOR, take your dose as soon as you remember, unless it is time to take the next dose. Use the doses at the right time.

If you stop taking Co-DOLOR

Do not stop taking these tablets immediately, it can make you fell restless or irritable. Talk to your doctor about reducing your dose gradually.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Co-DOLOR can cause side effects, although not everybody gets them.

The following side effects are reported with the following frequency:

Common (may affect up to 1 in 10 people)

- nausea
- vomiting
- constipation
- drowsiness
- confusion
- dizziness

Tolerance to these (except constipation) generally develops with long-term use.

Not known (frequency can not be estimated from the available data)

- haematological reactions including thrombocytopenia, leucopenia, pancytopenia, neutropenia, and agranulocytosis
- dry mouth
- sweating
- facial flushing
- headache
- vertigo
- bradycardia
- tachycardia
- palpitations
- orthostatic hypotension

- hypothermia
- severe allergic reactions
- airways muscle spasm and shortness of breath
- noise in the ears (tinnitus)
- restlessness
- changes of mood
- decreased libido or decreased potency
- hallucinations
- urinary disorders
- miosis
- lack of appetite
- muscle rigidity (after high doses)
- raised intracranial pressure
- liver damage
- seizure
- depression
- euphoria
- dependence to codeine
- a serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2).

Very rare (may affect up to 1 in 1000 people)

- pancreatitis

Adverse effects of paracetamol are rare and usually mild. Skin rashes and other hypersensitivity reactions occur occasionally. Very rare cases of serious skin reactions have been reported.

Regular, prolonged use of Co-DOLOR may lead to addiction and tolerance.

If you get these side effects or any side effect not listed in this leaflet, talk to your doctor or pharmacist.

Reporting of side effects:

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects via the National Agency of Drugs and Medical Devices website www.akbpm.gov.al/formulari-raportimi. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE CO-DOLOR

Keep this medicine out of the sight and reach of children.

Do not use Co-DOLOR after the expiry date which is stated on the package.

Store in temperature less than 25°C!

Keep Co-DOLOR away from light and humidity!

6. OTHER INFORMATION

What Co-DOLOR 500 mg / 30 mg tablets contain

The **active substances** are paracetamol and codeine phosphate hemihydrate.

Each tablet contains 500 mg paracetamol and 30 mg codeine phosphate hemihydrate.

The **excipients** are: microcrystalline cellulose, sodium starch glycolate, magnesium stearate, colloidal anhydrous silica, talc, pregelatinized starch, povidone.

Content of the pack

Carton box with 20 and 30 tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

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