

Package leaflet: Information for the user

Co-Tipol 500mg / 30mg Hard Capsules paracetamol/ codeine phosphate hemihydrate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Co-Tipol is and what it is used for
2. What you need to know before you take Co-Tipol
3. How to take Co-Tipol
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1. What Co-Tipol is and what it is used for

Co-Tipol is a pain killer (analgesic) used for the treatment of moderate to severe pain. It is a mixture of two drugs, paracetamol and codeine phosphate hemihydrate. They are part of a group of medicines known as analgesics (pain killers).

Co-Tipol can be used in children over 12 years of age for the short-term relief of moderate pain that is not relieved by other painkillers such as paracetamol or ibuprofen alone.

This product contains codeine. Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain. It can be used on its own or in combination with other pain killers such as paracetamol.

2. What you need to know before you take Co-Tipol

- This product contains paracetamol and codeine phosphate hemihydrate. Do not take Co-Tipol with any other product that contains paracetamol or codeine phosphate.
- Contains paracetamol
- Do not take any other paracetamol-containing products
- Do not exceed the stated dose
- Immediate medical advice should be sought in the event of overdose, because of the risk of irreversible liver damage.

Do not take Co-Tipol:

- if you are allergic to paracetamol, codeine or any of the other ingredients of this medicine (listed in section 6)
- if you are suffering from breathing difficulties or have a chest or lung problem (particularly in children aged 12-18 years)
- if you have pneumonia
- if you are having an asthmatic attack
- if you are well advanced in pregnancy
- if you are at risk for premature delivery
- if you weigh less than 40 kg body or in children under 12 years of age
- if you are breast-feeding
- if you know that you metabolise very rapidly codeine into morphine

- for pain relief in children and adolescents (0-18 years of age) after removal of their tonsils or adenoids due to obstructive sleep apnoea syndrome

Warnings and precautions

Codeine is transformed to morphine in the liver by an enzyme. Morphine is the substance that produces pain relief. Some people have a variation of this enzyme and this can affect people in different ways. In some people, morphine is not produced or produced in very small quantities, and it will not provide enough pain relief. Other people are more likely to get serious side effects because a very high amount of morphine is produced. If you notice any of the following side effects, you must stop taking this medicine and seek immediate medical advice: slow or shallow breathing, confusion, sleepiness, small pupils, feeling or being sick, constipation, lack of appetite.

Do not take with any other paracetamol containing products.

Talk to your doctor or pharmacist before taking Co-Tipol

- if you have a history of alcohol or drug addiction
- if you have impaired consciousness (feel very sleepy),
- if you are suffering from conditions associated with increased intracerebral pressure (raised pressure in the brain),
- if you are using monoamine oxidase (MAO) inhibitors (medicines for the treatment of depression)
- if you are affected with ventilation disorders of your lungs due to chronic bronchitis or bronchial asthma.
- if you have suffered a heart attack
- if you have pancreatitis (inflammation of the pancreas)
- if you have had a cholecystectomy (gall bladder operation)
- if you are a child aged 12-18 years
- If you have glutathione deficiency
- If you are dehydrated or are suffering from chronic malnutrition
- If you weigh less than 50kg
- If you are elderly
- If you have Chronic alcoholism
- if you have impaired liver function (e.g. due to long-term alcohol abuse or inflammation of the liver),
- if you have congenital increase in blood bilirubin levels (Gilbert's syndrome or Meulengracht's disease which causes yellow jaundice that runs in families),
- if you have impaired kidney function (including dialysis-dependent patients).
- if you have low blood pressure

Important information about your medicine

- If large amounts of pain killers (analgesics) are taken for extended periods of time, or if these medicines are not used properly, they may cause headache, which should not be treated with increased doses.
- Habitual use of pain killers, especially of those containing more than one active ingredient, may lead to permanent damage to the kidney, which might result in renal failure (analgesic nephropathy).
- Prolonged regular use, except under medical supervision, may lead to physical and psychological dependence (addiction) and result in withdrawal symptoms such as restlessness and irritability, once the drug is stopped. If you find you need to use this product all the time, it is important to consult your doctor.

Children and adolescents

Co-Tipol should only be used in children aged 12-18 years of age if other painkillers such as ibuprofen or paracetamol (alone) are not effective. Co-Tipol is not for use in children under 12 years of age or less than 40kg body weight.

Use in children and adolescents after surgery

Codeine should not be used for pain relief in children and adolescents after removal of their tonsils or adenoids due to Obstructive Sleep Apnoea Syndrome.

Use in children with breathing problems

Codeine is not recommended in children with breathing problems, since the symptoms of morphine toxicity may be worse in these children.

Other medicines and Co-Tipol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, talk to your doctor if you are taking any of the following:

- any medicines containing codeine or paracetamol
- MAO inhibitors e.g. tranlycypromine. Co-Tipol should not be used within two weeks after the last administration of any MAO inhibitor.
- other CNS-depressing medicines such as tranquilizers or sleeping pills
- antihypertensives (used to treat high blood pressure)
- other analgesics e.g. salicylamides
- antihistaminics (used for the treatment of allergies or for cold relief)
- medicines used to treat mental and emotional disturbances
- antiepileptics (e.g. phenobarbital, phenytoin, carbamazepine, etc.)
- rifampicin (used to treat tuberculosis)
- chloramphenicol (an antibiotic)
- anticoagulants e.g. warfarin (used to stop blood clotting)
- medicines which delay stomach emptying (e. g. propantheline)
- zidovudine (AZT or retrovir, used to treat HIV)
- medicines accelerating gastric emptying (e.g. metoclopramide or domperidone)
- probenecid (used to treat gout)
- cholestyramine (used to lower cholesterol)
- tricyclic antidepressants (used for the treatment of depression)
- buprenorphine and pentazocine (used to treat pain)
- cimetidine (used to reduce stomach acid).
- Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.

Concomitant use of Co-Tipol and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However if your doctor does prescribe Co-Tipol together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

In patients who concomitantly receive medicines speeding up the degradation of drugs in the liver (enzyme induction) such as certain sleeping pills and antiepileptics (phenobarbital, phenytoin, carbamazepine, etc.) or rifampicin (drug against tuberculosis), otherwise safe doses of paracetamol (an ingredient of Co-Tipol) may cause liver damage. The same applies to alcohol abuse.

Co-Tipol with food, drink and alcohol

See under 'Method of administration'

Alcohol should not be taken while taking Co-Tipol, since it can increase side effects which can interfere with coordination and the ability to concentrate.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Do not take Co-Tipol if you are well advanced in pregnancy or if you are at risk for premature delivery

Co-Tipol contains codeine. Do not take Co-Tipol while you are breast-feeding. Codeine and morphine passes into breast milk.

Driving and using machines

Even if used properly, Co-Tipol may cause drowsiness, incoordination, or difficulty concentrating to the extent that the ability to drive a car, operate machinery or perform hazardous activities may be seriously effected.

3. How to take Co-Tipol

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Unless otherwise described by your doctor, the recommended dose is as follows:

Age	Single dose	Maximum daily dose (24 hours)
Adults (18 years and over)	1 - 2 hard capsules (equivalent to 500 - 1,000 mg of paracetamol and 30 - 60 mg of codeine phosphate hemihydrate)	Up to 8 hard capsules (equivalent to up to 4,000 mg of paracetamol and up to 240 mg of codeine phosphate hemihydrate)

The maximum daily dose must not be exceeded, and the interval between doses (if any further capsules are needed) should be at least six hours.

This medicine should not be taken for more than 3 days. If the pain does not improve after 3 days, talk to your doctor for advice.

Use in patients with liver problems, kidney problems or Gilbert's syndrome (Meulengracht's disease)

- Your dosage may be lower or the interval between doses may be longer.
- Patients with severe renal failure should not be given Co-Tipol at intervals less than eight hours.
- The maximum daily dose of paracetamol should not exceed 60mg/kg/day (up to a maximum of 2g per day) unless your doctor gives you different advice if you weigh less than 50 kg or if you suffer from chronic alcoholism, malnutrition or dehydration (see section 2)
- Experience has indicated that normal adult dosage is usually appropriate in the elderly. However in frail, immobile, elderly subjects or in elderly patients with renal or hepatic impairment, a reduction in the amount or frequency of dosing may be appropriate.

Use in children and adolescents

Age	Single dose	Maximum daily dose (24 hours)
Adolescents over 15 years	1 - 2 hard capsules (equivalent to 500 - 1,000 mg of paracetamol and 30 - 60 mg of codeine phosphate hemihydrate)	Up to 8 hard capsules (equivalent to up to 4,000 mg of paracetamol and up to 240 mg of codeine phosphate hemihydrate)
Children aged 12 to 15 years:	1 hard capsule (equivalent to 500 mg of paracetamol and 30 mg of codeine phosphate hemihydrate)	Up to 4 hard capsules (equivalent to up to 2,000 mg of paracetamol and up to 120 mg of codeine phosphate hemihydrate)

Co-Tipol hard capsules 500 mg/30 mg should not be given to children under 12 years or with a body weight less than 40 kg due to the risk of severe breathing problems. Special care should be taken with children 12-18 years of age as they are more likely to develop serious side-effects.

Method of administration

The capsules should be swallowed whole with fluid (preferably a glass of water [200 ml]). They should not be taken while lying down. The product may have a delayed onset of action if the capsules are taken after meals.

If you take more Co-Tipol than you should

If you (or someone else) take too much Co-Tipol, contact your nearest hospital emergency department or your doctor immediately, even if you feel well, because of the risk of delayed serious liver damage. An overdose is likely to cause feeling sick or being sick, headache, inability to pass urine, severe constipation, paleness, stomach pain, slow breathing rate, increased muscle tone, seizures and coma.

Medical advice should be sought immediately when the recommended doses of Co-Tipol have been exceeded even by a small amount and even if you feel perfectly well as paracetamol can cause severe liver damage without causing any symptoms at first.

If you forget to take Co-Tipol

If you forget to take Co-Tipol, you can take this dose at any time. Do not take the next dose before an interval of at least six hours. Do not take a double dose to make up for a forgotten capsule.

If you stop taking Co-Tipol

No special precautions are required, if Co-Tipol has been used properly.

Headache, fatigue, muscular pain, nervousness and other symptoms may occur after abrupt discontinuation of prolonged, improper use of large amounts of pain killers, and will subside after a couple of days. No pain killers should be taken within this period. The use of such drugs should not be resumed without a physician's advice.

4. Possible side effects

Like all medicines, this medicine can cause side-effects, although not everybody gets them.

Stop taking Co-Tipol and tell your doctor immediately or go to the emergency department at your nearest hospital if the following happens:

- an allergic reaction causing swelling of the lips, face or neck leading to severe difficulty in breathing, or severe skin rash or hives.

- you have difficulty breathing (slow or shallow breathing), sleepiness, confusion, narrow pupils, nausea or vomiting, constipation or lack of appetite.

These are very serious but rare side effects. You may need urgent medical attention or hospitalisation.

Very common: may affect more than 1 in 10 people

- nausea, vomiting, constipation
- fatigue, headache
- dizziness

Common: may affect up to 1 in 10 people

- sleepiness

Uncommon: may affect up to 1 in 100 people

- dry mouth
- sleep disturbances
- itching, reddening of the skin, hives
- shortness of breath
- buzzing in the ears

Rare: may affect up to 1 in 1,000 people

- increase in liver transaminases (enzymes in the liver)
- decrease in the number of blood platelets (blood clotting cells) and white blood cells (infection fighting cells).

Very rare: may affect up to 1 in 10,000 people

- very rare cases of serious skin reactions (including Stevens-Johnson syndrome) have been reported
- spasm of the airways with difficulty in breathing (analgesic asthma)
- decrease in the number or absence of granulocytes (infection fighting cells in the blood), decrease in the number of the cells of all systems involved in blood formation (all blood cells)
- hypersensitivity reactions such as swelling of the face, difficulty in breathing, sweating, nausea, fall in blood pressure including shock

Other side effects reported

- Patients receiving large doses or affected with increased intracerebral pressure or head injuries may develop respiratory depression (problems breathing) and disturbances of vision.
- Accumulation of fluid in the lungs was seen in patients on large doses (pulmonary oedema), especially in those with pre-existing disorders of lung function (chest problems).
- Patients taking large amounts often develop fall in blood pressure and fainting.
- Large doses have been reported to cause disturbances of vision.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse.

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

You can also report side effects directly via the national reporting system:

HPRA Pharmacovigilance

Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Co-Tipol

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

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions. Store in the original package in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Co-Tipol contains

The active substances are paracetamol and codeine phosphate hemihydrate.

Each hard capsule contains 500 mg of paracetamol and 30 mg of codeine phosphate hemihydrate.

The other ingredients are:

Talc, gelatin, titanium dioxide (E171), iron oxide red (E172), iron oxide yellow (E172).

What Co-Tipol hard capsules 500 mg/30 mg look like and contents of the pack

Co-Tipol are hard capsules consisting of a white and a yellowish orange section containing white powder.

Co-Tipol is available in blister packs of 10, 20 and 100 capsules and hospital packs of 200 and 1000 capsules.

Not all pack sizes may be marketed.

Marketing authorisation holder:

Clonmel Healthcare Ltd
Waterford Road
Clonmel, Co. Tipperary
Ireland

Manufacturer:

bene-Arzneimittel GmbH
Herterichstrasse 1
D-81479 Munich
Germany

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