INFORMATION FOR THE USER

Co-Tipol 500mg/30mg
SUPPOSITORIES
Paracetamol /
Codeine Phosphate Hemihydrate

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

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
- 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 overdosage, because of the risk of irreversible liver damage.

In this leaflet:
1. What Co-Tipol is and what it is used for.
2. Before you use Co-Tipol.
3. How to use Co-Tipol.
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5. How to store Co-Tipol.
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1. WHAT CO-TIPOL IS AND WHAT IT IS USED FOR

Your suppositories are called Co-Tipol. They are 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 is used for the treatment of moderate to severe pain.

2. BEFORE YOU USE CO-TIPOL

Do not use Co-Tipol if you:
- are hypersensitive (allergic) to paracetamol, codeine, soya or any of the other ingredients of Co-Tipol
- Co-Tipol contains soya lecithin. If you are allergic to soya or peanut, do not use this medicinal product
- have severe liver problems
- are in the late stages of pregnancy
- are at risk for premature delivery
- are breastfeeding
- are using an anticonvulsant
- have pneumonia
- are using monoamine oxidase (MAO) inhibitors (medicines for the treatment of depression)
- are using other medicines containing paracetamol or codeine phosphate
- are suffering from breathing difficulties or have a chest or lung problem (particularly in children aged 12-18 years)
- are someone who metabolises (breaks down) medicines very fast (see below)

Co-Tipol is not for use in children under 12 years of age or less than 43kg body weight.

Co-Tipol is not for use in children aged 12-18 years for treatment of symptoms after an operation for removal of tonsils or adenoids as part of treatment of sleep apnoea syndrome (frequent interruption of breathing during sleep)

Take special care with Co-Tipol

Tell your doctor before you start to take this medicine if you:
- have a history of alcohol or drug dependence
- have any impaired consciousness (feel very sleepy)
- are suffering from conditions associated with increased intracerebral pressure (raised pressure on the brain)
- are affected with problems with your lungs due to chronic bronchitis or bronchial asthma
- have undergone a cholecystectomy (gallbladder operation)
- have pancreatitis (inflammation of the pancreas)
- have suffered from a heart attack
- are a child aged 12-18 years as you are at increased risk of side effects

Tell your doctor before you start to take this medicine as you may require lower doses or longer dose intervals if you have:
- liver problems (e.g. due to long-term alcohol abuse or inflammation of the liver)
- congenital increase in blood bilirubin levels (Gilbert's syndrome or Meulengracht's disease which is a form of yellow jaundice that runs in families)
- kidney problems (including dialysis-dependent patients)
- 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).
- your doctor will monitor you at the start of treatment to avoid the possibility of overdosing. This applies especially to children aged 12-18 years, elderly patients and to persons with impaired kidney function or disorders of respiratory function.
- Owing to the genetic variability of liver enzymes which breakdown medicines, recommended amounts of codeine in some patients may lead to an increased formation of its breakdown product (morphine) and cause the clinical symptoms of morphine poisoning (see overdosage in section 3). That is why at the start of treatment some patients may be very sensitive and get more side effects than other patients. This applies especially to children 12-18 years, elderly patients and to persons with impaired kidney function or disorders of respiratory function (breathing or chest problems).
- Severe acute hypersensitivity reactions such as anaphylactic shock have very rarely been seen. Treatment should be discontinued at the earliest signs of hypersensitivity reactions to the use/ administration of Co-Tipol. This is a very serious but rare side effect.
Do not take Co-Tipol in combination with:
- any medicines containing codeine or paracetamol
- MAO inhibitors e.g. tranylcypromine. Co-Tipol should not be used within two weeks after the last administration of any MAO inhibitor.

Talk to your doctor if you are taking any of the following:
- other CNS-depressing medicines such as tranquilizers or sleeping pills
- antihypertensives (used to treat high blood pressure)
- other analesges e.g. salicylamides
- antihistamminics (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), otherwise safe doses of
- carbamazepine, etc.) or rifampicin (drug against tuberculosis), otherwise safe doses of
- paracetamol, etc.)
- 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)
- probenicid (used to treat gout)
- clofibrate (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)
- alcohol (do not drink alcohol while taking Co-Tipol)

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

The sedative effect of the product and its depressive action on respiration (effect on breathing) may be increased by the concomitant use of other CNS-depressing drugs such as tranquilizers and sleeping pills, antihypertensives (agents reducing high blood pressure) and other analgesics (pain-killers), antihistamminics (used for the treatment of allergies or for cold relief) or psychotherapeutic agents medicines for the treatment of allergies or for mental and emotional disturbances) as well as alcohol.

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.

Taking Co-Tipol with food and drink

Do not drink alcohol while using Co-Tipol.
Method of administration
the suppository should be inserted into the bowel.
the suppositories should be put deeply into the rectum after bowel movement. They may be warmed in the hand or dipped for a short time into hot water to improve sliding properties.
duration of treatment is as directed by your doctor.

Patients with liver problems, kidney problems, Sjögren’s syndrome or Meulengracht's disease your dosage may be lower or the interval between doses may be longer.
patients with severe renal failure (creatinine clearance below 10 ml/min) should not be given Co-Tipol at intervals less than eight hours.

Children
Co-Tipol suppositories should not be given to children under 12 years or below 43 kilograms of weight.
special care should be taken with children 12-18 years as they are more likely to develop serious side effects.
please consult your doctor or pharmacist, if you feel the effect of Co-Tipol is too strong or too weak.

If you use more Co-Tipol than you should
If you (or someone else) uses too much Co-Tipol, contact your nearest hospital casualty 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, faintness, 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 use Co-Tipol
Do not take a double dose to make up for a forgotten suppository.
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.

If you stop using Co-Tipol
No special precautions are required if Co-Tipol has been used properly.
headache, fatigue, muscular pain, nervousness and vegetative 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, Co-Tipol can cause side-effects, although not everybody gets them. Stop using the suppositories and tell your doctor immediately or go to the casualty 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 or your child have difficulty breathing (slow or shallow breathing), sleepiness, con-fusion, narrow pupils, nausea or vomiting, constipation or lack of appetite.

There are very serious but rare side effect. You may need urgent medical attention or hospitalisation.
The prolonged administration of large amounts increases the risk of producing dependence (addiction).

Very common:
• affects more than 1 user in 10

Common:
• affects 1 to 10 users in 100

Uncommon:
• affects 1 to 10 users in 1,000

Very rare:
• affects less than 1 user in 10,000

Not known:
Frequency cannot be estimated from the available data.

• very common:
  - nausea, vomiting, constipation
  - fatigue, mild headache
  - dizziness

• common:
  - mild sleepiness

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

• rare:
  - 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:
  - very rare cases of serious skin reactions (including Stevens-Johnson syndrome) have been reported.
  - spasm of the airways with difficulty in breathing (anaesthetic 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.
- Allergic reactions caused by non-fat phospholipids from soybeans are very rare.
- Large doses have been reported to cause disturbances of vision.
- Patients taking larger doses of Co-Tipol over a long period of time may become addicted.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 HPRA Pharmacovigilance, Earlsfort Terrace, Dublin D02 XP77, Ireland; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; e-mail: medsafety@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 out of the reach and sight of children.

Do not store above 25 °C.

Store in original package to protect from light.

Do not use Co-Tipol after the expiry date which is stated on the carton label and blister foil after EXP. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Co-Tipol contains

The active substances are paracetamol and codeine phosphate hemihydrate. Each suppository contains 500mg paracetamol and 30mg codeine phosphate hemihydrate.

The other ingredients are hard fat and soya lecithin.

What Co-Tipol suppositories look like and contents of the pack

Co-Tipol are white to ivory coloured, torpedo shaped suppositories.

Co-Tipol is available in blister packs of 10, 25 and 50 suppositories and hospital pack of 100 suppositories.

Not all pack sizes may be marketed.

Marketing authorization holder:

Carysfort Healthcare Limited
93 Carysfort Park
Blackrock
Co. Dublin A94 H2F3
Ireland

Marketing authorization number:

PA 1684/3/2

Manufacturer

bene-Arzneimittel GmbH
Hertenerchstrasse 1
D-81479 Munich
Germany

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