Package leaflet: Information for the user

Co-Tipol Max 1000mg/60mg 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 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 Max is and what it is used for

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

Co-Tipol Max 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 use Co-Tipol Max

- 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.

Do not use Co-Tipol Max:
- if you are allergic to paracetamol, codeine, soya or any of the other ingredients of this medicine (listed in section 6)
- for children under 12 years of age or less than 43kg body weight
- if you are well advanced in pregnancy
- if you are at risk for premature delivery
- if you are breastfeeding
- if you are having an asthmatic attack

- if you have pneumonia
- if you are suffering from disorders of the respiratory centre or the respiratory function (breathing difficulties or have a chest or lung problem) (particularly in children 12-18 years of age)
- if you are using any other medicines that contain paracetamol or codeine phosphate
- 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
- if you know that you metabolise very rapidly codeine into morphine

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 using Co-Tipol Max
- if you have a history of alcohol or drug addiction
- if you have any impaired consciousness (feel very sleepy)
- if you are suffering from conditions associated with increased intracerebral pressure (raised pressure on the brain)
- if you are using monoamine oxidase (MAO) inhibitors (medicines for the treatment of depression)
- if you are affected with problems with your lungs due to chronic bronchitis or bronchial asthma.
- if you have had a cholecystectomy (gallbladder operation)
- if you have pancreatitis (inflammation of the pancreas)
- if you have suffered from a heart attack.
- if you are a child aged 12-18 years as you are at increased risk of side effects
- 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 is a form of yellow jaundice that runs in families),
- if you have impaired kidney function (including dialysis-dependent patients).
- If you have low blood pressure
- 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).

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 43kg 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 Max
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. tranylcypromine. Co-Tipol Max 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 (called metabolic acidosis) that must have urgent treatment (see section 2).

Concomitant use of Co-Tipol Max 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 Max 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 Max) may cause liver damage. The same applies to alcohol abuse.

Co-Tipol Max with food, drink and alcohol
Alcohol should not be taken while using 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.

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

Driving and using machines
Even if used properly, Co-Tipol Max may modify the patient's reaction to an extent that the ability to drive a car, operate machinery or perform hazardous activities may be seriously impaired.

Co-Tipol Max contains soya lecithin
If you are allergic to soya or peanut, do not use this medicinal product.

3. How to use Co-Tipol Max
Always use 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	Body weight	Single dose	Maximum daily dose (24 hours)
Adults and children above 12 years of age	More than 43 kg	1 suppository (equivalent to 1,000 mg of paracetamol and 60 mg of codeine phosphate hemihydrate)	Up to 4 suppositories (equivalent to up to 4,000 mg of paracetamol and up to 240 mg of codeine phosphate hemihydrate)

The maximum daily dose (4 suppositories in 24 hours) must not be exceeded, and the interval between doses (if any further suppositories are needed) should be at least six hours.

This medicine should not be used 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 Max suppositories at intervals less than eight hours.
- 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
Co-Tipol Max suppositories should not be given to children under 12 years or less than 43 kilograms body weight due to the risk of severe breathing problems. Special care should be taken with children aged 12-18 years as they are more likely to develop serious side-effects.

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.

If you use more Co-Tipol Max than you should
If you (or someone else) uses too much Co-Tipol Max, 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 Max 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 Max
If you forget to take Co-Tipol Max, 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 suppository.

If you stop using Co-Tipol Max
No special precautions are required, if Co-Tipol Max 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, this medicine can cause side effects, although not everybody gets them.

Stop using the suppositories 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.
• if you or your child 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.

The prolonged administration of large amounts increases the risk of producing dependence (addiction).

Very common: may affect more than 1 in 10 people
- nausea, vomiting, constipation
- fatigue, mild headache
- dizziness

Common: may affect up to 1 in 10 people
- mild 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

Not Known (frequency cannot be estimated from the available data)
- A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2).

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.

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 directly via:
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 Max
Keep this medicine out of the sight and reach of children.

Do not store above 25 °C. Store in the original package in order to protect from light.

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.

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 Max contains
The active substances are paracetamol and codeine phosphate hemihydrate. Each suppository contains 1000mg paracetamol and 60mg codeine phosphate hemihydrate.

The other ingredients are hard fat and soya lecithin.

What Co-Tipol Max suppositories look like and contents of the pack
Co-Tipol Max are white to ivory coloured, torpedo shaped suppositories.

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

Not all pack sizes may be marketed.

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