

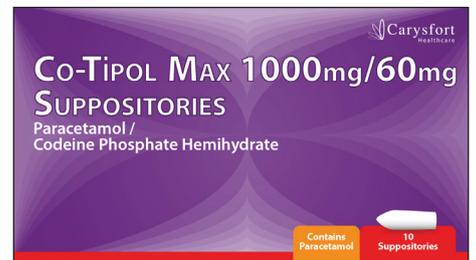


**New Co-Tipol 500mg/30mg, Co-Tipol Max 1000mg/60mg  
Suppositories Paracetamol / Codeine Phosphate Hemihydrate.**

<b>Co-Tipol 500mg/30mg Suppositories Paracetamol / Codeine Phosphate Hemihydrate.</b>			
Age	Body weight	Single dose	Maximum daily dose (24 hours)
Adults and Children above 12 years of age	More than 43kg	1 - 2 suppositories (equivalent to 500 - 1000mg of paracetamol and 30 - 60mg of codeine phosphate hemihydrate)	5 - 8 suppositories (equivalent to 2500 - 4000mg of paracetamol and 150 - 240mg of codeine phosphate hemihydrate)
Children 12-18 years: Co-Tipol is only suitable for use in children older than 12 years for treatment of acute moderate pain that cannot be relieved by other analgesics such as paracetamol and ibuprofen (alone). Not suitable for children under 18 years who have had tonsillectomy or adenoidectomy for treatment of obstructive sleep apnoea.			



<b>Co-Tipol Max 1000mg/60mg Suppositories Paracetamol / Codeine Phosphate Hemihydrate.</b>			
Age	Body weight	Single dose	Maximum daily dose (24 hours)
Adults and Children above 12 years of age	More than 43kg	1 suppository (equivalent to 1000mg of paracetamol and 60mg of codeine phosphate hemihydrate)	Up to 4 suppositories (equivalent to up to 4000mg of paracetamol and up to 240mg of codeine phosphate hemihydrate)
Children 12-18 years: Co-Tipol Max is only suitable for use in children older than 12 years for treatment of acute moderate pain that cannot be relieved by other analgesics such as paracetamol and ibuprofen (alone). Not suitable for children under 18 years who have had tonsillectomy or adenoidectomy for treatment of obstructive sleep apnoea.			



**New Co-Tipol 500mg/30mg, Co-Tipol Max 1000mg/60mg  
are the only Paracetamol / Codeine Phosphate  
Hemihydrate Suppositories available in Ireland.**



**Abbreviated Prescribing Information – see Summary of Product Characteristics for full details**

**Name of medicinal product:** Co-Tipol 500mg/30mg Suppositories, Co-Tipol Max 1000mg/60mg suppositories. Co-Tipol contains paracetamol / codeine phosphate hemihydrate. **Therapeutic indications:** Adults: Moderate to severe pain. Children 12-18 years: Co-Tipol is only suitable for use in children older than 12 years for treatment of acute moderate pain that cannot be relieved by other analgesics such as paracetamol and ibuprofen (alone). **Posology and Method of administration:** See dosing tables. The dose should be reduced or the interval between doses should be increased in the presence of impaired liver and/or kidney function and in subjects suffering from Gilbert's syndrome (Meulengracht's disease). Co-Tipol suppositories should be put deeply into the rectum after bowel movement. They may be warmed in the hand or dipped briefly into hot water to improve sliding properties. **Contraindications:** Co-Tipol is contraindicated in hypersensitivity to paracetamol, codeine, soybean (Co-Tipol suppositories contain soybean lecithin) or any of the other excipients, severe hepatocellular insufficiency (Child-Pugh  $\geq 9$ ), respiratory insufficiency, pneumonia, acute attack of asthma, women well advanced in pregnancy, risk for premature delivery, breastfeeding, known ultra-rapid metabolisers for CYP2D6, children under 18 years who have had tonsillectomy or adenoidectomy for treatment of obstructive sleep apnoea, children under 12 years, adults or children less than 40kg body weight, children with compromised respiratory function. **Warnings and precautions:** Co-Tipol should be used with caution in the following situations: opioid dependence, impaired consciousness, patients with hypovolaemia or hypotension, conditions associated with increased intracerebral pressure, treatment with MAO inhibitors, chronic obstructive airways disease, hepatocellular insufficiency (Child-Pugh  $< 9$ ), chronic alcohol abuse, severe renal failure (creatinine clearance below 10 ml/min) and in dialysis-dependent subjects, Gilbert's syndrome (Meulengracht's disease). Groups at increased risk of toxicity; fast metabolisers for CYP2D6, children 12-18 years, elderly patients, persons with impaired kidney function or disorders of respiratory function. Severe liver damage may result from exceeding the recommended dose. Caution in long-term use especially at higher dosages. **Interactions:** Co-Tipol may interact with the following: phenothiazines (chlorpromazine, thioridazine, perphenazine), antihistaminics (e. g. promethazine, meclozine), antihypertensives and other analgesics, drugs causing enzyme induction in the liver (phenobarbital, phenytoin, carbamazepine, etc.) as well as rifampicin. Co-Tipol may interact with chloramphenicol, anticoagulants, propantheline, metoclopramide, domperidone, zidovudine (AZT or retrovir), probenecid, salicylamides, cholestyramine, alcohol, tricyclic antidepressants, MAO inhibitors, opioid agonists and antagonists such as buprenorphine and pentacozine, cimetidine and other drugs influencing the liver metabolism. **Pregnancy:** Co-Tipol should only be used during pregnancy after balancing benefits against risks. Co-Tipol is contraindicated in women well advanced in pregnancy or at risk for premature delivery. Prolonged use of codeine may give rise to opioid dependence of the foetus. **Lactation:** Co-Tipol is not recommended in breast-feeding mothers. **Effects on ability to drive and use machines** Codeine may modify the patient's reaction to an extent that his/her ability to drive a car, operate machinery or perform hazardous activities is impaired. **Undesirable effects:** nausea, vomiting, constipation, dry mouth, increase in liver transaminases, fatigue, mild headache, dizziness, mild sleepiness, sleep disturbances, drug dependence, dose-related disturbances of visiomotor coordination and impaired visual acuity, respiratory depression, euphoria, pruritus, erythema, allergic exanthema, urticaria, severe allergic reactions including Stevens-Johnson syndrome, shortness of breath, bronchospasm (analgesic asthma), pulmonary oedema, fall in blood pressure and syncope, tinnitus, allergic thrombocytopenia, leucocytopenia, agranulocytosis, pancytopenia, hypersensitivity reactions. Soybean lecithin may induce allergic reactions very rarely. **Overdose:** Ingestion of excess paracetamol can cause hepatocellular necrosis. Ingestion of 5g or more of paracetamol may lead to liver damage if the patient has risk factors. Respiratory depression, hypotension and somnolence are characteristic symptoms of codeine overdose. Concomitant intake of other drugs and alcohol may increase the risk of toxicity. **Shelf life:** 5 years. **Special precautions for storage:** Do not store above 25°C. Store in the original package to protect from light **Marketing authorisation holder:** Carysfort Healthcare Limited, 93 Carysfort Park, Blackrock Co. Dublin, Ireland **Marketing authorisation number:** PA 1684/3/2-3 **Date of preparation:** March 2015