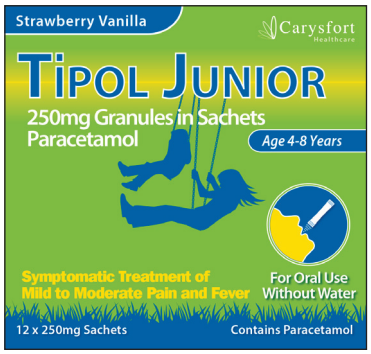
PINEWOOD HEALTHCARE

Tipol Granules in Sachets Paracetamol - For Oral Use Without Water

(Tip on the tongue and swallow) **www.tipol.ie**

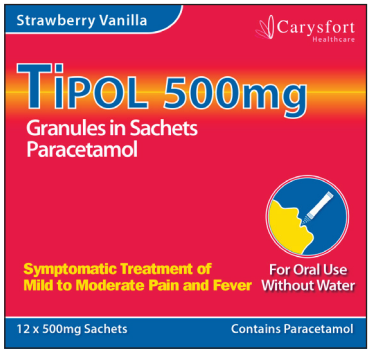
Dosing Table for Tipol Junior 250mg Granules in Sachets Paracetamol

Age	Body weight	Single dose	Maximum daily dose
4 to 8 years	17 to 25 kilograms	250mg Paracetamol (1 sachet)	1000mg Paracetamol (4 sachets)



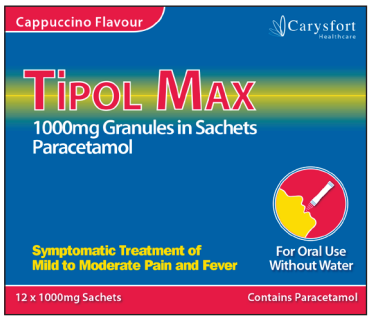
Dosing Table for Tipol 500mg Granules in Sachets Paracetamol

Age	Body weight	Single dose	Maximum daily dose
8 to 12 years	26 to 40 kilograms	500mg Paracetamol (1 sachet)	1500mg Paracetamol (3 sachets)
Children over 12 years and adults	> 40 kilograms	500 - 1000mg Paracetamol (1-2 sachets)	3000mg Paracetamol (6 sachets of 500mg)



Dosing Table for Tipol Max 1000mg Granules in Sachets Paracetamol

Age	Body weight	Single dose	Maximum daily dose
Children over 12 years and adults	> 40 kilograms	1000mg Paracetamol (1 sachet)	3000mg Paracetamol (3 sachets of 1000mg)



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Date of preparation: April 2016

MA Holder: Carysfort Healthcare

Abbreviated Prescribing Information. Further Information available on Request from the Marketing Authorisation Holder. See SPC for further details.

NAME OF THE MEDICINAL PRODUCTS: Tipol Junior 250mg granules in sachets, Tipol 500 mg granules in sachets and Tipol Max 1000mg granules in sachets **QUALITATIVE AND QUANTITATIVE COMPOSITION:** One sachet of Tipol Junior 250mg contains 250mg paracetamol, Tipol 500mg contains 500 mg paracetamol, Tipol Max 1000mg contains 1000mg paracetamol. Excipient(s): sorbitol (E420) (Tipol Junior 250mg, Tipol 500mg and Tipol Max 1000mg), sucrose (Tipol Junior 250mg and Tipol 500mg). **Pharmaceutical Form**: White or almost white granules in sachets. **Therapeutic indications** Symptomatic treatment of mild to moderate pain and fever. **Posology and method of administration** Doses depend on body weight and age; a single dose ranges from 10 to 15 mg/kg body weight. The total daily dose ranges from 60-75 mg/kg. The specific dose interval depends on the symptoms and the maximum daily dose. It should, however, not fall below 4 hours. Don`t use Tipol for longer than three days without medical advice. **Method of administration:** For oral use only. The granules should be taken directly into the mouth onto the tongue and should be swallowed without water. Do not take Tipol granules at a fed state. **Special groups of patients impaired liver or kidney function:** In patients with impaired hepatic or renal function or Gilbert's syndrome, the dose must be reduced or the dosing interval prolonged. **Chronic alcoholism**: Chronic alcohol consumption may lower the paracetamol toxicity threshold. **Elderly patients:** Dose adjustment is not required in the elderly. The daily effective dose must be considered, without exceeding 60 mg/kg/day (without exceeding 3 g/day) in the following situations: Adults weighing less than 50 kg, Hepatocellular insufficiency (mild to moderate), Chronic alcoholism, Dehydration, Chronic malnutrition, Impaired liver or kidney function. **Contraindications**: Hypersensitivity to paracetamol or to any of the excipients, Patients with severe hepatic dysfunction (Child-Pugh > 9). **Special warnings and precautions for use:** Avoid any concurrent medicinal product which contains paracetamol. Paracetamol should be administered only with particular caution under the following circumstances: hepatocellular insufficiency (Child-Pugh < 9), chronic alcohol abuse, severe renal insufficiency (creatinine clearance < 10 ml/min, Gilbert's syndrome (familial non-haemolytic jaundice), acute hepatitis, concomitant treatment with medicinal products affecting hepatic functions, glucose-6-phosphatedehydrogenase deficiency and haemolytic anaemia. Patients with rare hereditary problems of fructose intolerance (Tipol Junior, Tipol 500mg and Tipol Max), glucose-galactose malabsorption or sucrase-isomaltase insufficiency (Tipol Junior and Tipol 500mg) should not take this medicine. **Interaction with other medicinal products and other forms of interaction**: In patients concurrently taking probenecid, the paracetamol dose should be reduced. The metabolism of paracetamol is increased in patients taking enzyme-inducing medicinal products such as rifampicin and some antiepileptics (carbamazepine, phenytoin, phenobarbital, primidone). Concurrent administration of paracetamol and AZT (zidovudine) enhances the tendency to neutropenia. Concurrent intake of medicinal products that accelerate gastric emptying, such as metoclopramide, accelerates the absorption and onset of effect of paracetamol. Concurrent intake of medicinal products that slow gastric emptying can delay the absorption and onset of effect of paracetamol. Colestyramine reduces absorption of paracetamol. Repeated paracetamol intake enhances the effect of anticoagulants, particularly warfarin. Paracetamol can interfere with laboratory tests for serum uric acid using phosphotungstic acid and blood sugar tests using glucose-oxidase-peroxidase. Paracetamol increases the plasma levels of acetylsalicylic acid and chloramphenicol. **Fertility, pregnancy and lactation**: **Pregnancy**: During pregnancy, paracetamol should not be taken for longs periods, at high doses or in combination with other medicinal products, as safety of use in such cases is not established. **Lactation**: paracetamol is excreted into breast milk in small quantities. No undesirable effects on nursing infants have been reported. Therapeutic doses of this medicinal product may be used during breast-feeding. **Effects on ability to drive and use machine:** Paracetamol has no influence on the ability to drive and use machines. **Undesirable effects:** anaemia, non-haemolytic anaemia; bone marrow depression, thrombocytopenia, Oedema, acute and chronic pancreatitis, haemorrhage, abdominal pain, diarrhoea, nausea, vomiting, hepatic failure, hepatic necrosis, jaundice, pruritus, rash, sweating, purpura, angioedema, urticaria, nephropathies and tubular disorders. **Overdose**: Seek immediate specialist help even in the absence of symptoms and even with small overdoses because of the possibility of severe, irreversible liver damage. Increased risk of liver damage at smaller doses in patients on certain drugs, who use excess alcohol or who are glutathione deficient.

PA Number and Legal Classification: Tipol Junior 250mg PA 1684/4/1, Tipol 500mg PA 1684/4/2, Tipol Max 1000mg PA 1684/4/3. Tipol Junior 250mg: General Sales (2, 6, 10 and 12 pack), Pharmacy only (20, 24 pack); Tipol 500mg: General Sales (2, 6, 10, 12 pack), Pharmacy only (20, 24 pack); Tipol Max 1000mg: General Sales (2, 6 pack), Pharmacy only (10, 12 pack); not all pack sizes marketed. **MA Holder:** Carysfort Healthcare Limited, 93 Carysfort Park, Blackrock, Co. Dublin. **Date of preparation**: April 2016.

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