

Complete Range of Tipol Suppositories Paracetamol

Dosing Table for Tipol 75mg Suppositories Paracetamol.

Body weight	Age	First dose (equivalent dose of paracetamol)	Interval between doses	Max. daily dose (equivalent dose of paracetamol)
3-4 kilograms	<3 months	1 suppository (75 mg paracetamol)	8 to 12 hours 1 suppository (75 mg paracetamol)	2 suppositories (150 mg paracetamol)
4-5 kilograms	<3 months	1 suppository (75 mg paracetamol)	6 to 8 hours 1 suppository (75 mg paracetamol)	3 suppositories (225 mg paracetamol)
4 kilograms	>3 months	1 suppository (75 mg paracetamol)	6 to 8 hours 1 suppository (75 mg paracetamol)	3 suppositories (225 mg paracetamol)
5-6 kilograms	>3 months	1 suppository (75 mg paracetamol)	6 hours 1 suppository (75 mg paracetamol)	4 suppositories (300 mg paracetamol)



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Dosing Table for Tipol 125mg Suppositories Paracetamol.

Body weight (Age)	Single dose (equivalent dose of paracetamol)	Maximum daily dose (24 hours) (equivalent dose of paracetamol)
7 kilograms (6-7 months)	1 suppository (equivalent to 125 mg of paracetamol)	3 suppositories (equivalent to 375 mg of paracetamol)
8-12 kilograms (7 months - 2 years)	1 suppository (equivalent to 125 mg of paracetamol)	4 suppositories (equivalent to 500 mg of paracetamol)

The dosage interval must be at least 6 hours



GMS Code: 68183 **P**

Dosing Table for Tipol 250mg Suppositories Paracetamol.

Body weight (Age)	Single dose (equivalent dose of paracetamol)	Maximum daily dose (24 hours) (equivalent dose of paracetamol)
13-15 kilograms (children 2 - 4 years)	1 suppository (equivalent to 250 mg of paracetamol)	3 suppositories (equivalent to 750 mg of paracetamol)
16-25 kilograms (children 4 - 8 years)	1 suppository (equivalent to 250 mg of paracetamol)	4 suppositories (equivalent to 1,000 mg of paracetamol)

The dosage interval must be at least 6 hours



GMS Code: 68296 **P**

Dosing Table for Tipol 500mg Suppositories Paracetamol.

Body weight (Age)	Single dose (equivalent dose of paracetamol)	Maximum daily dose (24 hours) (equivalent dose of paracetamol)
26-32 kilograms (8-11 years)	1 suppository (equivalent to 500 mg of paracetamol)	3 suppositories (equivalent to 1500 mg of paracetamol)
33-43 kilograms (11 - 12 years)	1 suppository (equivalent to 500 mg of paracetamol)	4 suppositories (equivalent to 2000 mg of paracetamol)
more than 43 kilograms (children and youth from 12 years and adults)	1 or 2 suppositories (equivalent to 500 or 1000 mg of paracetamol)	8 suppositories (equivalent to 4000 mg of paracetamol)

The dosage interval must be at least 6 hours

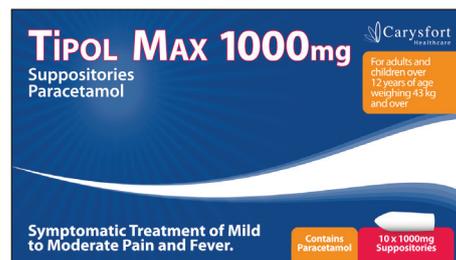


GMS Code: 68472 **P**

Dosing Table for Tipol Max 1000mg Suppositories Paracetamol

Body weight (Age)	Single dose (equivalent dose of paracetamol)	Maximum daily dose (24 hours) (equivalent dose of paracetamol)
more than 43 kilograms (Children from 12 years and adults)	1 suppository (equivalent to 1000 mg of paracetamol)	4 suppositories (equivalent to 4000 mg of paracetamol)

The dosage interval must be at least 6 hours



GMS Code: 68534 **P**



Abbreviated Prescribing Information (see SPC for full details)

Name of the Medicinal Products: Tipol 75 mg Suppositories, Tipol 125mg Suppositories, Tipol 250 mg Suppositories, Tipol 500mg Suppositories, Tipol Max 1000mg Suppositories. Tipol Suppositories contain paracetamol. Tipol 500mg Suppositories and Tipol Max 1000mg Suppositories contain Soya Lecithin. **Therapeutic Indications:** Symptomatic treatment of mild to moderate pain and/ or fever. **Posology and method of administration:** See dosing tables. The dosage interval depends on the symptoms and the maximum daily dose. If symptoms are persisting for more than three days medical attention must be received. Tipol suppositories should be put deeply into the rectum after bowel movement. They may be warmed up in the hands or dipped for a short time into warm water to improve their sliding properties. Special populations: Elderly patients: Dosage adjustment is not required. Impaired liver and kidney function: For patients with impaired liver and kidney function or Gilbert's syndrome the dose should be reduced or the interval between doses should be increased. Patients at increased risk of toxic liver effects: Elderly patients, infants, patients with chronic nutritional disorders, patients who are underweight, patients with liver or renal disease, patients taking excess alcohol or patients using medicines which are enzyme inducers are more likely to develop liver toxicity from paracetamol use. Even relatively small overdoses of paracetamol in these patients can cause serious liver toxicity which can be fatal. Children and adolescents: See dosing tables. **Contraindications:** Tipol must not be used by patients with known hypersensitivity to paracetamol or to any other excipients. Tipol 500mg Suppositories and Tipol Max 1000mg Suppositories contain soya which may cause allergic reactions. Severe hepatocellular insufficiency (Child-Pugh ≥ 9). **Special warnings and precautions for use:** To avoid the risk of overdose, it must be ensured that any concurrent medication does not contain paracetamol. In the following disorders, use paracetamol with caution: hepatocellular insufficiency (Child-Pugh < 9), chronic nutritional disorder, underweight, chronic alcohol abuse, severe renal insufficiency (creatinine clearance below 10 ml/min), Gilbert's syndrome (Meulengracht's disease). High fever, evidence of secondary infection and symptoms persisting for more than three days should receive medical attention. Medicinal products containing paracetamol should only be taken for a few days and not in large doses without a physician's or a dentist's advice. If analgesics are taken for extended periods of time or if these drugs are not used properly, they may cause headache which should not be treated with increased doses. In general, the habitual use of analgesics, in particular those containing more than one active ingredient, may lead to permanent damage to the kidney, which might result in renal failure (analgesic nephropathy). Headache, fatigue, muscular pain, nervousness and vegetative symptoms may occur after abrupt discontinuation of prolonged, improper use of large amounts of analgesics, and will subside after a couple of days. No analgesics should be taken within this period. The use of such medicinal products should not be resumed without a physician's advice. Immediate medical advice should be sought in the event of overdosage, because of the risk of irreversible liver damage. **Interaction with other medicinal products and other forms of interaction** Paracetamol should be used with caution with the following medications: warfarin and other coumarins, probenecid, liver inducers such as phenobarbital, phenytoin, carbamazepine and rifampicin, AZT (zidovudine), chloramphenicol, cholestyramine, chronic or acute alcohol intake, metoclopramide, domperidone and oral contraceptives. **Fertility, pregnancy and lactation:** Pregnancy: Under normal circumstances paracetamol may be used throughout pregnancy after balancing the therapeutic benefits against the possible risks. During pregnancy, paracetamol should not be used for prolonged periods of time, in high doses or in combination with other drugs, since its safety has not been established under these conditions. Lactation: Small amounts of orally given paracetamol are excreted in human milk. No deleterious effects or adverse reactions during lactation have been observed. Thus, paracetamol may be given to nursing women in therapeutic amounts. **Effects on ability to drive and use machines:** No unfavourable effects are to be expected. **Undesirable effects:** Increase in liver transaminases, changes of blood count such as thrombocytopenia and agranulocytosis, analgesic-induced bronchospasm, hypersensitivity reactions like erythema including urticaria and anaphylactic shock. Soybean lecithin may induce allergic reactions (Tipol 500mg Suppositories and Tipol Max 1000mg Suppositories contain soybean lecithin). **Overdose:** Elderly people, infants, persons with liver disease, chronic alcohol abuse and chronic nutritional disorders, people who are underweight and those concomitantly receiving other active substances which cause enzyme induction, are more at risk of intoxication. In such cases, overdosing may be fatal. Overdosing of paracetamol as a single dose in adults or children can cause hepatonecrosis, which may lead to total irreversible hepatonecrosis and, subsequently, to hepatocellular insufficiency, metabolic acidosis and encephalopathy. These conditions may result in coma and produce death. At the same time, increased concentrations of liver transaminases (AST, ALT), lactate dehydrogenase and bilirubin in combination with a prolonged prothrombin time were observed. These abnormalities may occur between 12 and 48 hours after administration of the drug. The clinical symptoms of hepatic damage are usually noted after two days and are most pronounced after 4 to 6 days. Acute renal failure and acute tubular necrosis may occur even in the absence of severe hepatic damage. Myocardial abnormalities and pancreatitis are among other symptoms that are unrelated to hepatic damage and have been observed after overdosing with paracetamol.

Shelf life: 5 years. **Special precautions for storage:** Do not store above 25°C.

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Marketing authorisation number: PA 1684/2/1-5

Date of preparation: December 2013