

Package leaflet: Information for the user

Tipol 500 mg granules in sachets

paracetamol

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

What is in this leaflet

1. What Tipol is and what it is used for
2. What you need to know before you take Tipol
3. How to take Tipol
4. Possible side effects
5. How to store Tipol
6. Contents of the pack and other information

1. What Tipol is and what it is used for

This product contains paracetamol

Paracetamol belongs to the pharmacotherapeutic group of analgesics (pain-reducing agents) which are acting simultaneously as antipyretics (fever-reducing agents) with weak anti-inflammatory effects.

Tipol is used to reduce fever and for the relief of mild to moderate pain.

2. What you need to know before you take Tipol

Do not take Tipol

- if you are allergic to paracetamol or any of the other ingredients of this medicine (listed in section 6).
- if you have severe liver disease.

Warnings and precautions

Talk to your doctor or pharmacist before taking Tipol:

- if you suffer from severe kidney or liver disease.
- if you have chronic alcoholism
- if you have glucose-6-phosphatedehydrogenase deficiency
- if you have haemolytic anaemia
- if you have Gilbert's syndrome (familial non-haemolytic jaundice)
- the hazards of overdose are greater in patients with non-cirrhotic alcoholic liver disease (liver disease caused by overuse of alcohol).
- do not exceed the recommended dose.

Prolonged or frequent use is discouraged.

Do not take any other paracetamol-containing products.

Do not exceed the stated dose

Immediate medical advice should be sought in the event of overdose, because of the risk of irreversible liver damage. Irreversible liver damage can develop even in patients who feel perfectly well after an overdose.

Prolonged use except under medical supervision may be harmful. In children treated with 60mg/kg daily of paracetamol, the combination with another antipyretic is not justified except in the case of ineffectiveness.

Caution is advised in the administration of paracetamol to patients with severe renal insufficiency (kidney failure) (creatinine clearance \leq 30mL/min (see section 4.2)) or hepatocellular insufficiency (liver failure) (mild to moderate).

The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease (liver disease related to alcohol overuse). Caution should be exercised in cases of chronic alcoholism. The daily dose should not exceed 2 grams in such case.

In the case of high fever, or signs of secondary infection or persistence of symptoms beyond 3 days, a re-evaluation of treatment should be made.

Paracetamol should be used with caution in cases of dehydration and chronic malnutrition (e.g. anorexia or severe weight loss). The daily effective dose must be considered, without exceeding 60 mg/kg/day (without exceeding 3 g/day for adults).

If your symptoms worsen or do not improve after 3 days, or with high fever you must contact a doctor.

Do not use paracetamol unless prescribed by your doctor if you have an addiction to alcohol or liver damage and do not use paracetamol together with alcohol. Paracetamol does not potentiate the effect of alcohol.

If you are taking other pain medication containing paracetamol do not use Tipol without first speaking to your doctor or a pharmacist.

Never take more of Tipol than recommended. A higher dose does not increase pain relief; instead it can cause serious liver damage. The symptoms of liver damage occur first after a few days. It is therefore very important that you contact your doctor as soon as possible if you have taken more Tipol than recommended in this leaflet.

In long-term, high-dose, incorrect use of painkillers, headaches may occur which may not be treated with higher doses of the medicine.

In general, habitual intake of painkillers, particularly a combination of several analgesic substances, can lead to permanent kidney damage with the risk of kidney failure (analgesic nephropathy).

Abrupt discontinuation following long-term, high-dose, incorrect use of painkillers may lead to headaches, fatigue, muscle pain, nervousness and autonomic symptoms (e.g. sweating, palpitations). These withdrawal symptoms resolve within a few days. Until this time, avoid further intake of painkillers and do not restart them without medical advice.

You should not take Tipol for long periods or at high doses without talking to your doctor or dentist.

Children and adolescents

Do not use this medicine in children under 10 years.

Other medicines and Tipol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Medicines that can affect the effects of Tipol:

- probenecid (a medicine used to treat gout)
- possibly liver-damaging medicines e.g. phenobarbital (sleeping tablets) phenytoin, carbamazepine, primidone (medicines used to treat epilepsy) and rifampicin (a medicine used to treat tuberculosis). Simultaneous use of these medicines and paracetamol can cause liver damage
- metoclopramide and domperidone (medicines used to treat nausea). These can increase the absorption and onset of effect of paracetamol.
- medicines that slow emptying of the stomach. These can delay the absorption and onset of effect of paracetamol.
- colestyramine (a medicine to reduce raised cholesterol). These can decrease the absorption and onset of effect of paracetamol. Therefore you should not take Colestyramine within an hour following paracetamol administration.
- blood-thinning medicines (oral anticoagulants, particularly warfarin). Repeated paracetamol intake for longer than one week enhances the bleeding tendency. Therefore long-term administration of paracetamol should only take place under medical supervision. Occasional paracetamol intake has no significant effects on bleeding tendency

Simultaneous use of paracetamol and AZT (zidovudine, a medicine used to treat HIV infections) increases the tendency to a reduction in the white blood cells (neutropenia). This can affect the immune system and increase the risk for infections. Tipol should therefore be used simultaneously with zidovudine only on medical advice.

Effect of the intake of paracetamol on laboratory tests
Tests for uric acid and blood sugar can be affected.

Tipol with alcohol

Do not drink alcohol while taking Tipol.

Pregnancy and breast-feeding

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 taking this medicine.

If necessary, Tipol can be used during pregnancy. You should use the lowest dose possible that reduces your pain and/or fever and use it for the shortest time possible. Contact your doctor if the pain and/or fever are not reduced or if your need to take Tipol more often.

During pregnancy, paracetamol should not be taken for long periods, at high doses or in combination with other medicinal products.

Therapeutic doses of paracetamol may be used during pregnancy or breast-feeding.

Driving and using machines

The use of Tipol has no influence on the ability to drive or use machines.

Tipol contains sorbitol and sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains 801 mg sorbitol in each sachet.

Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic

disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

3. How to take Tipol

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Paracetamol doses depend on body weight and age. A single dose ranges from 10-15 mg/kg body weight, given every 4 to 6 hours as required, and a maximum of 4 doses can be given in 24 hours.

The following table gives a guide to the recommended doses and dosing frequencies for Tipol 500mg granules based on the age and weight of the child.

Age (Body Weight)	Recommended Dose	Frequency
10-12 years (29kg–35kg)	500 mg Paracetamol (1 sachet)	Every 4-6 hours when necessary to a maximum of 4 doses in 24 hours
12 - 15 years (35kg–50kg)	500mg Paracetamol (1 sachet)	Every 4-6 hours when necessary to a maximum of 4 doses in 24 hours
children over 16 years and adults (50kg and over)	500 - 1000 mg Paracetamol (1 – 2 sachets)	Every 4-6 hours when necessary to a maximum of 4 doses in 24 hours

For children under 10 years other formulations and dose strengths are available which may be more appropriate.

- Do not give any more than 4 doses in any 24-hour period.
- Leave at least 4 hours between doses.
- Do not give this medicine to your child for more than 3 days without speaking to your doctor or pharmacist.
- Do not give to children under the age of 10 years.
- The max daily dose for adults who weigh less than 50kg should not exceed exceeding 60 mg/kg/day (or 2 g/day).

Method / Route of administration

Tipol is for oral use only.

The granules should be taken directly into the mouth onto the tongue and should be swallowed without water.

Special groups of patients

Impaired liver or kidney function

In patients with impaired liver or kidney function, the dose must be reduced or the dosing interval prolonged. Ask your doctor or pharmacist for advice.

Chronic alcoholism

Chronic alcohol consumption may lower the paracetamol toxicity threshold. In these patients, the length of time between two doses should be a minimum of 8 hours. Do not exceed 2 g paracetamol per day.

Elderly patients

Dose adjustment is not required in the elderly.

If you take more Tipol than you should

In the case of an overdose with Tipol please inform your doctor or emergency room. Overdosing has very serious consequences and can even lead to death.

Immediate treatment is essential, even if you feel well, because of the risk of delayed serious liver damage. Symptoms may be limited to nausea or vomiting and may not reflect the severity of overdose or the risk of organ damage.

If you forget to take Tipol

Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Rare: may affect up to 1 in 1,000 people

The following rare side effects may occur:

- Anaemia (low blood count)
- non-haemolytic anaemia and a condition of the bone marrow with disturbances in the production of blood cells (called bone marrow depression)
- thrombocytopenia (low platelets which help in blood clotting)
- acute and chronic pancreatitis (inflammation of the pancreas)
- allergic conditions
- urticaria (hives)
- anaphylactic reactions (severe allergic reaction which can cause swelling and difficulty breathing)
- stomach upset (nausea, vomiting, stomach pain)
- bleeding
- liver disease
- kidney disease

Very rare: may affect up to 1 in 10,000 people

Very rare cases of serious skin reactions have been reported.

Paracetamol has been widely used and reports of adverse reactions are rare and they are generally associated with overdose. 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 HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; 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 Tipol

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the sachet and on the carton after EXP. The expiry date refers to the last day of that month.

Do not store above 30° C.

Store in the original package in order to protect from light and moisture.

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 to protect the environment

6. Contents of the pack and other information

What Tipol contains

The active substance is:

paracetamol

1 sachet contains 500mg paracetamol

The other ingredients are:

Sorbitol (E 420)

Talc

Basic butylated methacrylate copolymer

Magnesium oxide light

Carmellose sodium

Sucralose

Magnesium stearate

Hypromellose

Stearic acid

Sodium laurilsulfate

Titanium dioxide (E 171)

N,2,3-Trimethyl-2-(propan-2-yl)butanamid,

Simeticone

Strawberry flavour (contains Maltodextrin, Gum arabic (E414), Natural & Nature Identical Flavouring substances, Propylenglycol (E1520), Triacetin (E1518), 3 Hydroxy-2-methyl-4H-pyran-4-on (E636))

Vanilla flavour (contains Maltodextrin, Natural & Nature Identical Flavouring substances, Propylenglycol (E1520), Sucrose)

What Tipol looks like and contents of the pack

Aluminium sachet with white or almost white granules.

Tipol is available in boxes with 2, 4, 6, 10, 12, 20, 24 sachets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Clonmel Healthcare Ltd.,
Waterford Road,
Clonmel,
Co. Tipperary,
Ireland

Manufacturer :

Losan Pharma GmbH
Otto-Hahn-Strasse 13, 79395 Neuenburg, Germany

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