



## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **Tipol 500 mg granules in sachets**

Paracetamol

**Read all of this leaflet carefully because it contains important information for you.**

This medicine is available without prescription. However, you still need to use Tipol carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 3 days.
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

#### **In this leaflet:**

1. What Tipol is and what it is used for
2. Before you take Tipol
3. How to take Tipol
4. Possible side effects
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### **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. BEFORE YOU TAKE TIPOL**

#### **Do not take Tipol**

- if you are allergic (hypersensitive) to paracetamol or any of the other ingredients of Tipol
- if you have severe liver disease.

#### **Take special care with Tipol**

- if you suffer from severe kidney or liver disease.
- 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.
- 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).

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 total dose of paracetamol should not exceed 3 g daily for adults and children weighing 50kg and more.

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.

### **Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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.

### **Pregnancy and breast-feeding**

Ask your doctor or pharmacist for advice before taking any medicine.

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.

### **Important information about some of the ingredients of Tipol:**

This medicinal product 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.

## **3. HOW TO TAKE TIPOL**

Always take Tipol exactly according to the directions in this package leaflet. You should check with your doctor or pharmacist if you are not sure.

The dose depends on the data in the following table. The dose of Tipol is based upon age and body weight; the usual dose is 10–15 mg paracetamol per kg body weight as a single dose, up to a total daily dose of 60-75 mg/kg body weight.

The respective dose interval depends on the symptoms and the maximum total daily dose. A dosing interval of at least 6 hours must be maintained, that means an administration of maximum 4 times per day.

If symptoms persist longer than 3 days, a doctor should be contacted.

Body weight (age)	Single dose	max. daily dose
26 kg – 40 kg (8 -12 years)	500 mg Paracetamol (1 sachet)	1500 mg Paracetamol (3 sachets)
> 40 kg (children over 12 years and adults)	500 - 1000 mg Paracetamol (1 – 2 sachets)	3000 mg Paracetamol (6 sachets of 500mg)

### Method / Route of administration

Tipol is for oral use only.

Do not take Tipol with food.

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.

#### Children and adolescents with small body weight

Paracetamol 500 mg is not suitable for children under 8 years of age and under 26 kg body weight respectively, since the dose strength for this age group is not suitable. For this patient group, other formulations and dose strength are available.

### 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.

An 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 product, ask your doctor or pharmacist.

## 4. POSSIBLE SIDE EFFECTS

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

The frequency “rare” means: affects 1 to 10 users of 10,000.

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)
- thrombocytopaenia (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

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.

## 5. HOW TO STORE TIPOL

Keep out of the reach and sight of children.

Do not use Tipol 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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment

## 6. FURTHER 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 Maltrodextrin, Gum arabic (E414), Natural & Nature Identical Flavouring substances, Propylenglycol (E1520), Triacetin (E1518), 3 Hydroxy-2-methyl-4H-pyran-4-on (E636))

Vanilla flavour (contains Maltrodextrin, 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, 6, 10, 12, 20, 24 sachets

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and manufacturer**

Marketing Authorisation Holder:

Carysfort Healthcare Ltd.

93 Carysfort Park, Blackrock, Co. Dublin, Ireland

Phone: 00 353 (0) 1 2882332

Manufacturer :

Losan Pharma GmbH

Otto-Hahn-Strasse 13, 79395 Neuenburg, Germany

**This medicinal product is authorised in the Member States of the EEA under the following names:** Epsimol Erdbeer/Vanille 500 mg Granulat in Beuteln in Germany

**This leaflet was last approved in {MM/YYYY}**

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