

## **Package leaflet: Information for the user**

### **TIPOL 125 mg Suppositories paracetamol**

**For infants (6 months to 2 years) with a body weight of 7 kg or more**

**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 the symptoms worsen or do not improve after three 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.
- Contains paracetamol
- 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.

#### **In this leaflet**

1. What Tipol is and what it is used for
2. What you need to know before you use Tipol
3. How to use 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**

Tipol contains paracetamol which belongs to a group of medicines known as analgesics. Paracetamol is a medicine that relieves pain and reduces fever.

Tipol is used in infants with a body weight of 7 kg or more to treat:

- mild to moderate pain and fever.

#### **2. What you need to know before you use Tipol**

##### **Do not use Tipol**

- If your child is allergic (hypersensitive) to paracetamol or any of the other ingredients of Tipol (See section 6, Contents of the pack and other information).
- If your child weighs less than 7 kilograms.
- If your child has **severe liver problems**.

#### **Warnings and precautions**

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

##### **Speak to your doctor if you or your child has:**

- moderate liver problems;
- severe kidney problems;
- a rare inherited metabolic disease, named Gilbert's disease (also known as Meulengracht's disease) which is accompanied by elevated bilirubin-levels in the blood (this causes yellow jaundice that runs in families).

- severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

Elderly patients or patients who have inadequate intake of food or weight loss for any reason (e.g. caused by starvation, anorexia or serious illness) are more prone to serious toxic liver effects from paracetamol.

Under these circumstances, you should seek your doctor's advice before using the medicine.

### **Important information about your medicine**

If Tipol is taken over an extended period of time or not used as directed, headache may occur. This should not be treated by taking increased dosages of the drug. In general, regular long-term use of Tipol, especially in combination with other pain medications from the same class (such as aspirin or ibuprofen) may cause substantial kidney damage leading to the risk of kidney failure.

### **Using other medicines**

Please tell your doctor or pharmacist if your child is taking / using or has recently taken / used any other medicines, including medicines obtained without prescription.

### **Do not use Tipol in combination with:**

- any other medicines that contain paracetamol.

The use of Tipol increases the risk of adverse reactions to

- medicines enhancing the degradation of drugs in the liver, which may cause liver damage. For example sleeping tablets/sedatives and antiepileptics (such as phenobarbital, carbamazepine, phenytoin), as well as rifampicin (a drug against tuberculosis).
- probenecid (used to treat gout).
- chloramphenicol (an antibiotic).
- cholestyramine (used to treat diarrhoea or raised cholesterol)
- warfarin (used to prevent blood from clotting)
- metoclopramide or domperidone (used to suppress nausea or vomiting)
- oral contraceptives.
- zidovudine (an anti-viral medication). Patients taking this medicine along with Tipol may be more susceptible to having a lower number of white blood cells.
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

Tipol may influence the results of some blood sugar tests.

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

This is not applicable for the Tipol suppositories since it is intended for use in infants weighing 7 kg or more, however ask your doctor or pharmacist for advice before taking / using any medicine.

### **3. How to use Tipol**

Always use Tipol exactly as directed in this leaflet. You should check with your doctor or pharmacist if you are not sure.

Tipol® 125 mg suppositories are suitable for infants weighing 7 kg or more.

**Infants (6 months to 2 years) weighing 7 kilograms or more:**

- **Please consult your doctor if the treatment exceeds 72 hours.**
- Doses depend on body weight and age; a single dose ranges from 10 to 15 mg/kg body weight to a maximum of 60 mg/kg for total daily dose.
- The specific dose interval depends on the symptoms and the maximum daily dose.
- There should be at least a six-hour interval between doses.

**Unless otherwise prescribed by your doctor, the usual dose is:**

<b>Body weight (Age)</b>	<b>Single dose (equivalent dose of paracetamol)</b>	<b>Maximum daily dose (24 hours) (equivalent dose of paracetamol)</b>
7 kg (6 – 7 months)	1 suppository (equivalent to 125 mg of paracetamol)	3 suppositories (equivalent to 375 mg of paracetamol)
8 – 12 kg (7 months – 2 years)	1 suppository (equivalent to 125 mg of paracetamol)	4 suppositories (equivalent to 500 mg of paracetamol)

Do not exceed the maximum daily dose in a 24 hour period. The interval between doses should be at least 6 hours.

**Method of administration**

- The suppositories are for rectal use and should be inserted deeply into the rectum after bowel movement.
- The suppositories may be warmed up in the hands or dipped for a short time into warm water to improve the lubrication quality.

Please consult your doctor or pharmacist, if you feel the effect of Tipol is too strong or too weak.

**Patient with liver problems or moderate kidney problems**

Speak with your doctor before giving this medicine to your child in these cases. The dose should be reduced or the interval between doses should be increased in patients with impaired liver and kidney function or those with Gilbert's syndrome.

**Patients with severe kidney problems**

Speak with your doctor before giving this medicine to your child. If you or your child has severe kidney problems (creatinine clearance < 10 ml/min), you must allow at least 8 hour intervals in between doses.

**If you use more Tipol than you should**

Nausea, vomiting and severe abdominal pain may be the early signs of an overdose. Seek medical advice immediately, **even if the symptoms seem to be improving as overdosage can cause irreversible liver damage.** Your physician will take appropriate measures.

**If you forget to use Tipol**

Do not use 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 evaluation of side effects is based on the following incidence rates:

<b>Very common:</b>	affects more than 1 user in 10
<b>Common:</b>	affects 1 to 10 users in 100
<b>Uncommon:</b>	affects 1 to 10 users in 1,000
<b>Rare:</b>	affects 1 to 10 users in 10,000
<b>Very rare:</b>	affects less than 1 user in 10,000
<b>Not known:</b>	Frequency cannot be estimated from the available data.

**The following side effects may occur:**

Rare (affects 1 to 10 users in 10,000):

- Increase in liver transaminases (may indicate liver damage).

Very rare (affects less than 1 user in 10,000):

- Reduction in blood platelets, which increases risk of bleeding or bruising (thrombocytopenia).
- Severe reduction in the number of white blood cells which makes infections more likely (agranulocytosis).
- Difficulty in breathing or wheezing (bronchospasm - analgesic asthma) in predisposed persons.
- Allergic (hypersensitivity) reactions from common skin rash to hives and a serious allergic reaction which causes difficulty in breathing or dizziness (anaphylactic shock).
- Very rare cases of serious skin reactions have been reported.

Not known (frequency cannot be estimated from the available data):

- A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2).

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

HPRA Pharmacovigilance

Website: [www.hpra.ie](http://www.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 store above 25 °C.

Do not use this medicine after the expiry date which is stated on the strip and the carton after EXP. The expiry date refers to the last day of that month.

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 protect the environment.

**6. Contents of the pack and other information**

**What Tipol contains**

The active substance is paracetamol.

Each suppository contains 125 mg of paracetamol

The other ingredient is hard fat.

**What Tipol looks like and contents of the pack**

White to ivory coloured suppository with a length of approximately 26mm.

Tipol is available in packs containing 10 suppositories and in hospital-size packing containing 10 x 10 suppositories.

Not all pack sizes may be marketed.

**Marketing authorisation holder**

Clonmel Healthcare Ltd  
Waterford Road  
Clonmel, Co. Tipperary  
Ireland

**Manufacturer**

bene-Arzneimittel GmbH  
Herterichstrasse 1-3  
D-81479 Munich, Germany

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