

PARALIN125mg

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 Paralin 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.
- If after 3 days of fever or 5 days of pains, your symptoms get worse or do not improve, you must see a doctor.
- 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 Paralin is and what it is used for
2. Before you use Paralin
3. How to use Paralin
4. Possible side effects
5. How to store Paralin
6. Further information

1. What Paralin is and what it is used for

Paralin suppositories is part of the class of medicines known as analgesics-antipyretics. Paracetamol is used to relieve mild or moderate pains and fever.

2. Before you use Paralin

Do not use Paralin

- if you are allergic (hypersensitive) to paracetamol or any of the other ingredients of Paralin suppositories;
- if you suffer from hepatocellular insufficiency or active hepatic disease;
- If you have glucose-6-phosphate dehydrogenase deficiency;
- if you have a recent history of rectitis, anusitis or proctorrhagia.

Take special care with Paralin

- if you suffer from liver diseases, including viral hepatitis (hepatotoxicity risk of paracetamol increases); hepatic functions monitoring is recommended in long-term treatment and when large doses of paracetamol are taken.
- if you suffer from severe renal impairment (only in long-term treatment with large doses of paracetamol, the occasional use is considered acceptable);
- if you use this medicine together with other medicines (see Using other medicines);
- if you have diarrhea.

Using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription. Association with other medicines containing paracetamol is not recommended. In particular, caution is recommended in case of concomitant administration with other medicines. Ask your doctor in case you also use:

- medicines that induce hepatic enzymes, such as certain medicines for sleep inducing, medicines for epilepsy treatment (for example glutetamide, phenobarbital, fenitoin, carbamazepin), rifampicin (used to treat tuberculosis), herbal preparations containing St John's wort;
- medicines that cause the slowing of digestive tract, such as propantheline;
- cholestyramine (bile acids resin, used to reducing cholesterol levels in blood);
- metoclopramide, domperidone (used to improve the nausea and vomiting symptoms);
- nonsteroidal anti-inflammatory drugs (mainly acetylsalicylic acid);
- zidovudine (used to treat HIV);
- probenecid (used to treat gout);
- warfarin or coumarin derivatives (medicines called anticoagulants, used to prevent the blood clotting);
- lamotrigine (used to treat epilepsy);
- chloramphenicol (antibiotic).

If you intend to do laboratory tests, tell your doctor that you are taking paracetamol.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine. Paralin is intended for use in children under 12 years of age, but if a girl or a woman of childbearing age uses this medicine, the following warnings should be considered:

- the medicine may be used in therapeutic doses during pregnancy, in short-term treatment, but it can be administered only if your doctor recommends it.
- paracetamol crosses the placenta and is excreted in the breast milk but not in a significant amount.

However, paracetamol should be used only in prescribed doses; long-term treatment should be avoided.

Driving and using machines

Paralin has no influence on ability to drive and use machines.

3. How to use Paralin

Always use Paralin exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Suppositories with paracetamol are administered rectally. Suppositories should be administered whole. Breaking of suppositories before use is not recommended. Since the recommended dose in children up to six months of age is less than the amount of active substance in Paralin 125mg suppositories, dosage forms of strengths suitable for this age should be used.

- Children of 6 to 12 months of age (7-10 kg)

The recommended dose is 125 mg of paracetamol (one suppository of Paralin 125mg) 1-4 times daily.

The interval between administrations: 4 - 6 hours.

Maximum dose per day: 500 mg of paracetamol (4 suppositories of Paralin 125mg)

- Children of 1 to 3 years of age (10-15 kg)

The recommended dose is 250 mg of paracetamol (2 suppositories of Paralin 125mg) 1-3 times daily.

The interval between administrations: 4-8 hours.

Maximum dose per day: 750 mg of paracetamol (6 suppositories of Paralin 125 mg)

- Children of 3 to 6 years of age (15-22 kg)

The recommended dose is 250 mg of paracetamol (2 suppositories of Paralin 125 mg) 1-4 times daily.

The interval between administrations: 4-8 hours.

Maximum dose per day: 1000 mg of paracetamol (8 suppositories of Paralin 125 mg)

- Children of 6 to 9 years of age (22-30 kg)

The recommended dose is 250-500 mg of paracetamol (2 to 4 suppositories of Paralin 125 mg) 3 times daily.

The interval between administrations: 4-8 hours.

Maximum dose per day: 1500 mg of paracetamol (12 suppositories of Paralin 125 mg)

- Children of 9 to 12 years of age (30-40 kg)

The recommended dose is 250-500 mg of paracetamol (2 to 4 suppositories of Paralin 125 mg) 4 times daily.

The interval between administrations: 4-8 hours.

Maximum dose per day: 2000 mg of paracetamol (16 suppositories of Paralin 125 mg).

Assessment of diagnosis and treatment is necessary if you still have pain after 5 days of use, fever after 3 days of use or if you get fever again after 3 days.

Renal impairment

In case of a renal impairment the doses should be adjusted by your doctor.

Hepatic impairment

In patients with mild hepatic impairment no dosage adjustment is necessary.

If you use more Paralin than you should

Administration in excess of any medicine can have severe consequences. No overdose was reported after paracetamol suppositories use. Cases of overdose were reported only for oral forms of paracetamol. If your child or another person accidentally ingests more suppositories, you should know that acute intoxication with paracetamol cause gastrointestinal disorders (diarrhea, loss of appetite, nausea, vomiting, abdominal cramps or pains), increased sweating. Severe symptoms may occur 24 to 48 hours after overdose ingestion. Hepatic encephalopathy (with mental disorders, confusion, agitation, stupor) convulsions, respiratory depression, coma, cerebral oedema, coagulation disorders, gastrointestinal bleeding, disseminated intravascular coagulation, hypoglycaemia, metabolic acidosis, and cardiovascular collapse may develop in time. Besides toxic liver damage, paracetamol may cause renal tubular necrosis or kidney failure (oligo-anuria with hematuria or cloudy urine). If you suspect an overdose tell your doctor or contact the nearest hospital emergency department.

If you forget to use Paralin

If you forgot to use a dose, use the medicine as soon as you remember. However, if it is time for the next dose, use only that dose. It is important not to use a double dose to make up for the forgotten dose.

If you have further questions regarding this product, tell your doctor or pharmacist.

4. Possible Side Effects

Like all medicines, Paralin can cause side effects, although not everybody gets them. The side effects have been classified depending on the frequency:

Very common:	affects more than 1 in 10 patients treated
Common:	affects less than 1 in 10 patients treated
Uncommon:	affects less than 1 in 100 patients treated
Rare:	affects less than 1 in 1000 patients treated
Very rare:	affects less than 1 in 10000 patients treated
Not known:	cannot be estimated from the available data

Common

- rectal redness.

Uncommon

- rash and urticaria.

Rare

- reduction in the number of platelets or white blood cells or red blood cells;
- allergic reactions such as angioedema, difficulty in breathing, bronchospasm, sweating, nausea, low blood pressure, shock. About 5 to10% patients who have asthma induced by acetylsalicylic acid may experience the same reactions when using paracetamol;
- hepatitis;
- rise of blood creatinine levels (secondary to hepato- renal syndrome), renal impairment. Results of a case-control study suggested that frequent use (daily or weekly) of paracetamol may be associated with the occurrence of bronchial asthma. However in patients diagnosed with bronchial asthma the use of paracetamol is not contraindicated when is used in recommended doses.

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 Paralin

Keep out of the reach and sight of children.

Do not use Paralin after the expiry date which is stated on the carton after EXP.

The expiry date refers to the last day of that month.

Store below 25°C, in the original package.

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 Paralin contains

- The active substance is paracetamol. Each suppository contains paracetamol 125 mg.
- The other ingredients are: hard fat.

What Paralin looks like and contents of the pack

Paralin are yellowish-white torpedo-shaped suppositories, with homogeneous appearance.

Outer carton with 1 PVC/PE strip of 6 suppositories.

The holder of trademark and Marketing Authorization is
“**BioActiveT, United Kingdom.**”

