

Package leaflet: Information for the patient

Paracetamol Slavia 500 mg tablets
Paracetamol

Read all 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 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 5 days when treating joint pain, after 3 days when treating fever, or after 2 days when treating sore throat.

What is in this leaflet:

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

1. What Paracetamol Slavia is and what it used for

Paracetamol Slavia contains paracetamol and is part of the group of analgesic-antipyretic drugs (relieves pain and reduces body temperature in case of fever).

Paracetamol Slavia is indicated for the symptomatic treatment of fever and for the symptomatic treatment of mild to moderate pain in adults, adolescents and children over 12 years of age, such as: headaches, toothaches, muscle or joint pain, menstrual pain and the symptomatic treatment of fever.

You must talk to a doctor if you do not feel better or if you feel worse after 5 days when treating joint pain, after 3 days when treating fever, or after 2 days when treating sore throat.

2. What you need to know before you use Paracetamol Slavia

Do not use Paracetamol Slavia:

- if you are allergic to paracetamol, propacetamol hydrochloride (precursor of paracetamol) or any of the other ingredients of this medicine (listed in section 6);
- if you suffer from an active liver disease or liver damage;
- in children under 12 years of age.

Warnings and precautions

Talk to your doctor or pharmacist before using Paracetamol Slavia if any of the situations mentioned

below apply to you or have applied to you:

- if you frequently drink alcohol or suffer from liver disease, including viral hepatitis (increased risk of hepatotoxicity);
- if you have Gilbert's syndrome (mild jaundice);
- if you have severe renal failure (only in the case of long-term treatment with high doses, occasional treatment is acceptable);
- if you have pre-existing liver damage, in the case of long-term treatment with high doses, monitoring of liver function is necessary;
- if you have glucose-6-phosphate dehydrogenase deficiency (enzyme deficiency);
- in case of lack of appetite, excessive appetite or excessive weight loss;
- in case of dehydration, decreased body fluids;
- if you are a man and are undergoing treatment for low fertility.

Children and adolescents

Do not use this medicine in children under 12 years of age, due to the inappropriate strength and pharmaceutical form for this age group.

Other medicines and Paracetamol Slavia

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

To avoid the risk of overdose, check that any other medicines you are taking (including those available with or without a prescription) do not contain paracetamol or propacetamol hydrochloride.

In particular, tell your doctor about the use of paracetamol at the same time as:

- medicines that produce a sleep similar to that of the physiological one (hypnotics);
- medicines capable of suppressing or reducing the frequency of epileptic seizures (antiepileptics), such as glutethimide, phenobarbital, phenytoin, carbamazepine;
- medicines used in the treatment of tuberculosis (tuberculostatics), such as rifampicin, as paracetamol may cause increased liver toxicity;
- medicines that slow gastric emptying (such as propantheline), as the therapeutic effect of paracetamol may be delayed;
- medicines used in the treatment of high cholesterol (such as cholestyramine); paracetamol should be taken 1 hour before or 4 hours after cholestyramine;
- medicines used to treat gastrointestinal disorders and nausea and vomiting (such as metoclopramide and domperidone), as they accelerate the absorption of paracetamol;
- non-steroidal anti-inflammatory drugs (mainly acetylsalicylic acid), as in high doses they increase the risk of kidney damage;
- oral contraceptives, as they may increase the elimination of paracetamol;
- medicines used in the treatment of HIV infections (such as zidovudine), as an increase in the tendency to decrease blood neutrophils and toxic liver damage has been reported;
- medicines used in the treatment of gout (such as probenecid), as they cause an almost two-fold decrease in the elimination of paracetamol;
- anticoagulant medicines (which thin the blood), such as warfarin or coumarin derivatives, as prolonged treatment, simultaneously with high doses of paracetamol, increases the bleeding risk of coumarin anticoagulants (occasional doses have no significant effect);
- medicines used in the treatment of epilepsy (such as lamotrigine), as paracetamol reduces the effectiveness of lamotrigine;
- antibiotics (such as chloramphenicol), as a clear slowdown in its elimination may occur, associated with increased toxicity.

The risk of paracetamol toxicity may be increased in patients receiving treatment with other potentially hepatotoxic drugs or enzyme-inducing drugs.

If you are going to have certain laboratory tests, tell your doctor that you are taking paracetamol.

Paracetamol Slavia with food, drinks and alcohol

There are no known interactions of paracetamol with food or drinks.

You should avoid drinking alcoholic beverages during long-term treatment with high doses, as chronic alcohol consumption increases the risk of liver damage. In patients with chronic alcoholism there is a risk of hepatotoxicity in the case of prolonged administration of high doses of paracetamol.

It is recommended to use the medicine with a sufficient amount of liquid (approximately 200 ml for adults, if possible).

Pregnancy, fertility and breast-feeding

Pregnancy

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, Paracetamol Slavia can be used during pregnancy. However, you should be given the lowest possible dose that reduces your pain and/or fever, and the medicine should be taken for the shortest possible time. Consult your doctor if your pain and/or fever does not decrease or if you need to take this medicine more often.

Fertility

If you are undergoing treatment for infertility, please consult your doctor to determine the appropriateness of taking Paracetamol Slavia.

Breast-feeding

In humans, paracetamol is excreted in milk in small quantities.

Paracetamol Slavia can be used, with caution, during breast-feeding.

Driving and using machines

Paracetamol Slavia does not affect the ability to drive or use machines.

3. How to use Paracetamol Slavia

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. You should talk to your doctor or pharmacist if you are not sure.

This pharmaceutical form is only indicated for use in adults and adolescents aged 12 years and over.

Dosage

Adults (including the elderly) and adolescents over 16 years of age (weighing over 50 kg):

The recommended dose is 500-1000 mg paracetamol (1-2 tablets Paracetamol Slavia) every 4 hours, administered as needed. Administration at intervals of less than 4 hours is not recommended.

In general, the dose of 3 g paracetamol (6 tablets Paracetamol Slavia) per day should not be exceeded.

The maximum recommended daily dose for adults is 4 g paracetamol (8 tablets Paracetamol Slavia) within 24 hours.

The maximum single dose (administered once) is 1 g (2 tablets).

Children aged 12 to 15 years (weighing 33-50 kg):

The recommended dose is 500 mg paracetamol (1 tablet Paracetamol Slavia) once; do not exceed 3-4 tablets within 24 hours.

It is not recommended to take the medicine at intervals of less than 4 hours. Do not take more than 4 doses per day.

Children under 12 years of age

This medicine is not indicated for children under 12 years of age.

It is recommended to take paracetamol in pharmaceutical forms and concentrations appropriate to the age.

Method of administration

Paracetamol Slavia is administered orally only.

The tablet is administered with a sufficient amount of liquid (approximately 200 ml for adults, if possible).

In children, there should be a regular interval between administrations both day and night, preferably 6 hours, but not less than 4 hours.

In adults, an interval of at least 4 hours between administrations is recommended.

Duration of treatment

It is necessary to consult a doctor if:

- the pain being treated, especially joint pain, persists for more than 5 days;
- the fever persists for more than 3 days and the symptoms worsen;
- severe pharyngitis persists for more than 2 days and is accompanied or followed by fever, headache, rash, nausea or vomiting.

Special patient groups

Patients with kidney problems

In case of moderate renal insufficiency: the recommended dose is 500 mg paracetamol (1 tablet Paracetamol Slavia), repeated every 6 hours.

In case of severe renal insufficiency: the recommended dose is 500 mg paracetamol (1 tablet Paracetamol Slavia), repeated every 8 hours.

Patients with liver problems

If you have liver problems, please consult your doctor. You should not exceed the dose of 2 g paracetamol (4 Paracetamol Slavia tablets) per day.

In patients with liver failure, the dose should be reduced or the interval between doses prolonged.

The maximum daily dose should not exceed 60 mg/kg body weight/day (not to exceed 2 g/day), in the following situations:

- adults weighing less than 50 kg;
- chronic or acute compensated liver damage, especially in those patients with mild to moderate hepatocellular insufficiency;
- Gilbert's syndrome (familial hyperbilirubinemia);
- chronic alcoholism;
- chronic malnutrition (low hepatic glutathione reserves);
- dehydration.

Elderly

No dosage adjustment is usually necessary in elderly patients.

If you take more Paracetamol Slavia than you should

If you have taken more Paracetamol Slavia than the recommended dose, contact your doctor immediately or go to the emergency room of your nearest hospital. It is important to tell your doctor, even if you feel well. Symptoms such as nausea, vomiting, loss of appetite, paleness, malaise and profuse sweating occur within the first 24 hours. Acute ingestion of a paracetamol overdose of 7.5 g or more in adults or 140 mg/kg body weight in children can be fatal due to serious and irreversible damage to the kidneys and liver. If a person has taken too many Paracetamol Slavia tablets, there is a risk of delayed serious liver damage.

If you forget to take Paracetamol Slavia

If you forget to take a dose, take another dose as soon as you remember, and after 4-6 hours resume your usual treatment. Do not take more than one dose every 4 hours. 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.

You should stop taking Paracetamol Slavia and see a doctor immediately if you experience symptoms such as swelling of the face, tongue and throat, difficulty swallowing, red and itchy skin and difficulty breathing.

The following side effects have been reported during post-marketing experience, but their frequency is unknown (cannot be estimated from the available data):

- thrombocytopenia (decreased number of blood platelets), leukopenia (abnormally decreased number of white blood cells), neutropenia (decreased number of certain types of white blood cells);
- diarrhoea, abdominal pain;
- increased serum liver enzymes;
- anaphylactic shock (sudden severe allergic reaction involving the whole body), Quincke's edema, hypersensitivity reaction;
- decreased INR values, increased INR values;
- urticaria, erythema (redness of the skin), rash;
- hypotension (as a symptom of anaphylaxis);
- acute generalised exanthematous pustulosis;
- toxic epidermal necrolysis;
- Stevens-Johnson syndrome (severe allergic reaction consisting of rash, fever and enlarged lymph nodes).

Reporting of side effects

If you get any side effects, please talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet. You can also report side effects directly via the national reporting system, details of which are published on the website of the National Agency for Medicines and Medical Devices in Romania <http://www.anm.ro/>.

By reporting side effects, you can help provide additional information on the safety of this medicine.

5. How to store Paracetamol Slavia

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 carton after "EXP". The expiry date refers to the last day of that month.

Store this medicine below 25°C, in the original packaging.

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 Paracetamol Slavia contains

- The active substance is paracetamol. Each tablet contains 500 mg of paracetamol.
- The other ingredients are: pregelatinised starch, povidone, sodium starch glycolate, stearic acid.

What Paracetamol Slavia looks like and contents of the pack

Paracetamol Slavia is presented in the form of convex tablets, white to off-white in colour, with a diameter of 12 mm.

Box with a PVC/Al blister of 10 tablets

Box with 2 PVC/Al blisters of 10 tablets each.

Marketing authorisation holder and manufacturer

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