

Package leaflet: Information for the user

Pamol Novum 500 mg film-coated tablets

paracetamol

RX

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

OTC

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

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have 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, pharmacist or nurse. 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 within 3 days with fever and 5 days with pain.

What is in this leaflet

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

1. What [Invented name] is and what it is used for

[Invented name] contains paracetamol which relieves pain and reduces fever.

RX

[Invented name] is used to relieve fever and pain conditions, e.g. fever during cold, headache, toothache, period pain, muscle and joint pain, rheumatic pain and high fever (hyperpyrexia).

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[To be adjusted nationally due to legal status]

Adults and adolescents over 40 kg (over 12 years): [Invented name] is used to relieve temporary fever and pain conditions, e.g. fever during cold, headache, toothache, period pain, muscle and joint pain.

[Invented name] is suitable for people with sensitive stomach or ulcers and people at high risk of developing bleeds.

OTC

You must talk to a doctor if you do not feel better or if you feel worse within 3 days with fever and 5 days with pain.

2. What you need to know before you use [Invented name]

Do not use [Invented name]

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

Warnings and precautions

If you take other pain-relieving medicines containing paracetamol, do not take [Invented name] without first talking to a doctor or pharmacist.

Never take more [Invented name] than what is stated in the dosing instructions in section 3 or ordained by your doctor. *Higher doses than recommended will not increase pain relief, instead it will pose a risk of very severe liver damage.* The symptoms of liver damage usually appear after a few days. It is therefore important that you contact a doctor immediately if you have taken too much, *even if you feel well.*

Do not take [Invented name] without a doctor's prescription if you have alcohol problems or liver damage and, also do not take [Invented name] with alcohol. The euphoric effect of alcohol does not increase through the use of [Invented name].

Prolonged or frequent use of pain-relieving medicines can cause headache. If that happens, stop taking the medicine and talk to your doctor.

Talk to your doctor before taking [Invented name]:

- if you have a kidney or liver disease
- if you have a deficiency of an enzyme called glucose-6-phosphatedehydrogenase
- if you have a disease called Gilbert's syndrome
- if you have asthma and at the same time are sensitive to aspirin (acetylsalicylic acid)
- if you are dehydrated or malnourished
- if you are underweight
- if you have a low number of red blood cells caused by abnormal breakdown (haemolytic anemia)
- if you have a severe infection such as sepsis, since this increases the risk for metabolic acidosis. Signs of metabolic acidosis includes: deep, rapid or forced breathing; nausea, vomiting; loss of appetite. Contact your doctor immediately if you experience a combination of these symptoms.

Some fragile elderly may need a reduced dose.

During treatment with [Invented name], tell your doctor straight away:

If you have 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).

Other medicines and [Invented name]

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

Never use multiple pain-relieving medicines at the same time without asking your doctor or pharmacist.

[Invented name] can affect or be affected by other medicinal products/herbal remedies:

- metoclopramide (used to treat nausea and vomiting)

- warfarin (anticoagulant, used to thin the blood). Contact your treating doctor if taking more than 2 tablets [Invented name] (à 500 mg) per day for 5 days in a row. There is a risk that the effect of warfarin will be affected
- probenecid (used for gout)
- medicines used to treat epilepsy:
 - phenytoin
 - phenobarbital
 - carbamazepine
- rifampicin (used to treat tuberculosis)
- cholestyramine (used to treat hyperlipidaemia). The medicines should be taken with at least one hour gap
- chloramphenicol for injection (used to treat bacterial infections). (However, chloramphenicol used to treat infections of the eye and [Invented name] can be used together.)
- St John's Wort extract (included in some (traditional) herbal medicines and remedies)
- flucloxacillin (used to treat infections), due to a serious risk of blood and fluid abnormality (called metabolic acidosis due to high anion gap,) that must have urgent treatment (see section 2, Warnings and precautions).

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, [Invented name] can be used during pregnancy. You should use the lowest possible dose that reduces your pain and/or fever and use it for the shortest time possible. Contact your doctor or midwife if the pain and/or fever are not reduced or if you need to take the medicine more often.

This medicine passes into breast milk but is unlikely to affect breast-feeding babies. However, consult your doctor if you are taking [Invented name] more than occasionally.

Driving and using machines

[Invented name] does not affect your ability to drive or use machines.

[Invented name] contains sodium

This medicine contains 176 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 8.8 % of the recommended maximum daily dietary intake of sodium for an adult.

Talk to your doctor or pharmacist if you need 3 or more tablets daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

3. How to use [Invented name]

RX

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

OTC

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

Note! Doses higher than those recommended involve serious risk for severe liver damage.

The recommended dose is:

Adults and adolescents over 40 kg (over 12 years): 1-2 tablets every 4-6 hours, up to a maximum of 8 tablets in 24 hours.

OTC

Contact your doctor if you do not feel better or if you feel worse within 3 days with fever and 5 days with pain.

Some fragile elderly may need a reduced dose.

If you have impaired hepatic or kidney function or have Gilbert's syndrome you should ask your doctor for the suitable dosage, since you might need a reduced dose.

[Invented name] can be taken regardless of meals.

If you take more [Invented name] than you should

If you take too much of the medicine, or if a child has taken the medicine by mistake, seek immediate medical help from doctor, hospital or National (local) Poisons Information Centre for evaluation of risk and counseling.

Paracetamol overdose involve serious risk for severe liver damage. There is a risk of liver damage even if you feel well.

In order to avoid liver damage, it is essential to get medical antidote treatment by doctor as early as possible.

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

4. Possible side effects

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

If any of the following side effects occur, stop taking the medicine and seek medical advice immediately:

Rare (may affect up to 1 in 1 000 people):

- Angioedema, severe allergic reaction:
 - swollen face, tongue or throat
 - difficulty swallowing
 - hives and difficulty in breathing
- Allergic reactions like rash and hives
- Liver damage. This can be severe and include symptoms like tiredness, nausea, vomiting, gastric problems and loss of appetite.

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

- Bleeding from skin and mucous membranes and bruises, general lethargy, tendency for inflammation (infections) especially sore throat and fever due to changes in blood composition (reduced number of white blood cells and blood platelets)
- Severe difficulty in breathing with gasping breath in patients sensitive to acetylsalicylic acid or other non-steroidal anti-inflammatory drugs (NSAID)
- Pallor, tiredness, and jaundice due to severe anaemia
- Serious skin reactions have been reported.
Stevens-Johnson's syndrome, a life-threatening reaction with flu-like symptoms and painful rash on skin, in mouth, eyes and genitals.
Toxic epidermal necrolysis, life-threatening reaction with flu-like symptoms and blisters on skin, in mouth, eyes and genitals.
Acute generalised exanthematous pustulosis, sudden blisters appearing on large skin areas accompanied with fever
- Drug induced skin inflammation
- Anaphylactic reaction: hypersensitivity reaction with fever, rash, swollenness and sometimes decrease in blood pressure.

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).

Other side effects that may occur:

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

- Renal side effects, cloudy urine
- Allergic dermatitis, rash, itch, sweating, redness
- Liver damage.

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 [the national reporting system listed in Appendix V](#). By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store [Invented name]

Keep this medicine out of the sight and reach of children [and adolescent](#).

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

This medicine does not require any special storage conditions.

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 [Invented name] contains

- The active substance is paracetamol.
Each film-coated tablet contains 500 mg paracetamol.
- The other excipients are:
Tablet core: sodium hydrogen carbonate, maize starch, pregelatinised maize starch, povidone, potassium sorbate (E 202), talc (E 553b), croscarmellose sodium, stearic acid.
Film-coating: titanium dioxide (E 171), polydextrose (E 1200), hypromellose (E 464), triacetin (E 1518), macrogol, carnauba wax (E 903).

What [Invented name] looks like and contents of the pack

White oval shaped film-coated tablet with 'P' embossed on one side and plain on other side.

Tablet dimensions: 19 x 9 mm.

Blister packs: 10, 20, 100, 300 film-coated tablets.

Bottles with a screw cap: 100, 300 film-coated tablets.

The bottle contains a pouch of silica gel desiccant, do not remove this from the bottle.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This leaflet was last revised in

2026-04-10

[Detailed information on this medicine is available on the web site of {MA/Agency}](#)

