

PACKAGE LEAFLET: Information for the patient

PROPARA

Solution for infusion – 1000 mg / 100 ml

(Paracetamol)

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 or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes worse or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Propara is and what it is used for
2. Before you use Propara
3. How to use Propara
4. Possible side effects
5. How to store Propara
6. Further information

1. WHAT PROPARA IS AND WHAT IT IS USED FOR

Propara contains the active substance paracetamol. It is indicated as an analgesic (relieves pain) and antipyretic (reduces temperature) for the short-term treatment of:

- moderate pain, especially after surgery;
- fever.

2. BEFORE YOU USE PROPARA

Do not use Propara if you:

- are hypersensitive to paracetamol or to any of the excipients of Propara;
- are hypersensitive to propacetamol (an analgesic and a prodrug of paracetamol);
- suffer from a severe liver damage.

Take special care with Propara

Talk to your doctor before using Propara.

Care should be taken:

- if you suffer from kidney or liver dysfunction, or if you abuse alcohol;
- if you suffer from an inherited disorder of liver function called “Meulengracht Gilbert syndrome”;
- if you suffer from glucose-6-phosphate dehydrogenase deficiency;
- if you are taking other medicines containing paracetamol;
- if you suffer from malnutrition or are receiving parenteral nutrition.

Talk to your doctor before treatment if you have any of the above conditions.

To relieve the pain, switch to tablets or syrups instead of Propara as soon as possible.

Taking other medicines

Please contact your doctor or pharmacist if you are taking or you have recently taken other drugs, including those taken without a prescription.

You should not take other medicines containing paracetamol if you are taking Propara in order not to exceed the recommended daily dose. Inform your doctor if you are taking other medicines containing paracetamol.

Do not forget to inform your doctor if you have been given another drug during the Propara treatment, especially the following:

- probenecid (medicine to treat gout);
- salicylamide (pain reliever);
- rifampicin (antibiotic);
- barbiturates;
- tricyclic antidepressants;
- antiepileptics (i.e. carbamazepine, phenytoin, phenobarbital, primidone);
- chloramphenicol (antibiotic);
- oral contraceptives;
- zidovudine (medicine to treat HIV);
- oral anticoagulants;
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe kidney impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine.

If necessary, Propara can be used during pregnancy. However, the lowest possible dose should be given to you to reduce pain and/or your fever, and it should be given to you for the shortest time possible. Tell your doctor if the pain and/or fever are not reduced or if you need to take the medicine more often.

Propara can be used during breastfeeding.

Driving and using machines

Propara does not affect the ability to drive or use machines.

Important information about some of the excipients of Propara

Propara contains:

- sodium metabisulfite, which may rarely cause severe hypersensitivity reactions and bronchospasms.
- about 29 mg sodium (main component of cooking/table salt) in each 100 ml bottle, equivalent to about 1.5 % of the recommended maximum daily dietary intake of sodium for an adult.

3. HOW TO USE PROPARA

This medicine is administered by intravenous infusion.

Your doctor will administer Propara to you by drip infusion and must monitor you carefully before the end of the infusion, to avoid air getting into the veins.

Propara is recommended for adults, adolescents and children weighing more than 33 kg (approximately 11 years old).

Dosing according to the patient's weight (refer to the dosage table below):

Patient's weight	Dose to be administered	Administration volume	Maximum volume for administration based on weight limits	Maximum daily dose*
> 33 kg – ≤ 50 kg	15 mg / kg	1.5 ml / kg	75 ml	60 mg / kg, not more than 3 g
> 50 kg with additional risk factors for hepatotoxicity	1 g	100 ml	100 ml	3 g
> 50 kg without additional risk factors for hepatotoxicity	1 g	100 ml	100 ml	4 g

* The maximum daily dose shown in the table is for patients not taking other products containing paracetamol and should be adjusted accordingly.

The minimum interval between each administration should be at least 4 hours.

The minimum interval between each administration in patients with severe renal insufficiency should be at least 6 hours.

The maximum daily dose should not exceed 3 g in adults with liver failure, chronic alcoholism, chronic malnutrition (low liver glutathione levels) or dehydration.

Not more than 4 doses should be administered in 24 hours.

RISK OF THERAPEUTIC ERRORS

Be careful to avoid dosing errors due to confusion between milligrams (mg) and milliliters (ml), which can cause accidental overdose and death.

Propara is given by infusion (drop by drop) into a vein in 15 minutes.

If you have the impression that the effect of Propara is too strong or too weak, talk to your doctor.

If you take more Propara than you should

If you take more Propara than you should, talk to your doctor or pharmacist straight away.

In case of overdose, symptoms usually appear within the first 24 hours and include: nausea, vomiting, loss of appetite, pallor and abdominal pain; if this happens immediate medical advice should be taken due to the risk of irreversible liver damage.

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

4. POSSIBLE SIDE EFFECTS

Like all other drugs, Propara may cause side effects, although not everybody manifests them.

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

- changes in laboratory test results (abnormally high levels of liver enzymes found in blood tests). If this happens, inform your doctor as regular blood tests may be needed;
- low blood pressure (hypotension);
- malaise.

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

- decreased numbers of blood cells (platelets, white blood cells), which can lead to bleeding of nose or gums and an increased risk of infections. If this happens, inform your doctor because regular blood tests may be needed;
- allergic reactions from simple skin rashes or hives to severe allergic reactions (anaphylactic shock); possible symptoms include swelling of the face, lips, tongue or other parts of the body and shortness of breath, difficulty breathing or temporary narrowing of the airways in the lungs (bronchospasm). If this happens, please inform your doctor immediately;
- serious skin reactions.

Unknown frequency (it is not known how common they are):

- rapid heartbeat (tachycardia);
- redness of the skin, rash, itching.

Effects on laboratory tests

Treatment with Propara may change the results of some laboratory tests for uric acid, such as blood glucose tests.

If any of the effects get worse or if you notice any side effects not mentioned in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE PROPARA

Keep out of the sight and reach of children!

Do not use Propara after the expiry date which is stated on the package.

Single use only.

Store in the original packaging to protect it from light!

Before administration, Propara must be visually inspected.

6. FURTHER INFORMATION

What Propara contains

The active substance is: paracetamol.

One bottle 100 ml contains 1000 mg paracetamol.

The excipients are: mannitol, citric acid monohydrate, dibasic sodium phosphate, sodium metabisulfite, hydrochloric acid, sodium hydroxide, water for injection.

Content of the pack

Carton box with a glass bottle of 100 ml sealed with a rubber closure and an aluminium cap.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

Tel.: +355 4 23 89 602

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