

Package leaflet: Information for the patient

Paracetamol 10 mg/mL solution for infusion 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, pharmacist or nurse.
- 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.

What is in this leaflet:

1. What Paracetamol 10 mg/mL solution for infusion is and what it is used for
2. What you need to know before you use Paracetamol 10 mg/mL solution for infusion
3. How to use this medicine
4. Possible side effects
5. How to store Paracetamol 10 mg/mL solution for infusion
6. Contents of the pack and other information

1. What Paracetamol 10 mg/mL solution for infusion is and what it is used for

This medicine contains the active substance paracetamol.

This medicine is an analgesic agent (it relieves pain) and an antipyretic agent (it reduces body temperature). It is used in the short-term to treat moderate pain, particularly post-surgery pain, and to treat fever.

10-mL bag is indicated in newborns at term, infants and children weighing less than or equal to 10 kg.

50-mL bag is indicated in infants and children weighing more than 10 kg and less than or equal to 33 kg.

100-mL bag is indicated in adults, adolescents and children weighing more than 33 kg.

2. What you need to know before you use Paracetamol 10 mg/mL solution for infusion

Do not use Paracetamol 10 mg/mL solution for infusion

- if you are allergic (hypersensitive) to paracetamol or to any of the other ingredients of this medicine (listed in section 6).
- if you are allergic (hypersensitive) to propacetamol (another analgesic agent used for infusions, a precursor of paracetamol).
- if you suffer from serious liver disease.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using this medicine.

Take special care with Paracetamol 10 mg/mL solution for infusion if you

- are taking other paracetamol-containing medicines;
- suffer from liver disease, Gilbert disease
- have severe reduced kidney function
- suffer from chronic and excessive alcohol consumption
- suffer from chronic malnutrition
- are dehydrated

- weight less than 50 kg
- have deficiency in glucose-6-phosphatase dehydrogenase (which can cause excessive breakdown of red blood cells, a blood disease)

Before starting treatment, tell your doctor if any of the above situations applies to you.

Your doctor will take care not to give you higher doses than those recommended. This can lead to serious liver damage.

Use a suitable oral analgesic treatment as soon as this route of administration is possible. Prolonged or frequent use of this medicine is not recommended.

During treatment with Paracetamol 10 mg/mL solution for infusion, tell your doctor straight away if:

- 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 Paracetamol 10 mg/mL solution for infusion

This medicine contains paracetamol: this should be taken into account if you are using other paracetamol-based medicines, so that you do not exceed the recommended daily dose (see section below). Tell your doctor if you are taking any other paracetamol-containing medicines.

Tell your doctor, pharmacist or nurse if you are using or have recently used or might use any other medicines, in particular with:

- medicines containing probenecid (used in the treatment of gout): a reduction in the dose of paracetamol should be considered.
- medicines containing salicylamide (used to treat pain): a dose adjustment may be necessary.
- medicines that activate liver enzymes: strict control of the dose of paracetamol is necessary to avoid liver damage.
- oral anticoagulants (used to thin the blood): closer monitoring of the effect of the anticoagulant may be necessary.
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before taking this medicine.

Pregnancy and breast-feeding

If necessary, this medicine can be used during pregnancy. You should use the lowest possible dose that reduces your pain and/or your fever and use it for the shortest time possible. Contact your doctor if the pain and/or fever are not reduced or if you need to take the medicine more often. Your doctor will assess whether this treatment is appropriate and may be used while breast-feeding.

Ask your doctor, pharmacist or nurse for advice before taking any medicine.

Driving and using machines

Paracetamol has no or negligible influence on the ability to drive and use machines.

Paracetamol 10 mg/mL solution for infusion contains sodium.

This medicine contains 25.2 mg sodium (main component of cooking/table salt) in each 10-mL bag. This is equivalent to 1.26 % of the recommended maximum daily dietary intake of sodium for an adult. This medicine contains 126 mg sodium (main component of cooking/table salt) in each 50-mL bag. This is equivalent to 6.3 % of the recommended maximum daily dietary intake of sodium for an adult. This medicine contains 252 mg sodium (main component of cooking/table salt) in each 100-mL bag. This is equivalent to 13 % of the recommended maximum daily dietary intake of sodium for an adult.

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

3. How to use Paracetamol 10 mg/mL solution for infusion

This medicine will be administered to you by a healthcare professional. Always use this medicine exactly as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Dosage

The dose will depend on your weight and your general condition. Your doctor will calculate your body weight and will determine the dose you should receive.

Method of administration

RISK OF MEDICATION ERRORS

Take care to avoid dosing errors due to confusion between **milligram (mg)** and **milliliter (mL)**, which could result in accidental overdose and death.

This medicine will be given by infusion into one of your veins. The infusion will last approximately 15 minutes.

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

If you use more Paracetamol 10 mg/mL solution for infusion than you should

In case of an overdose, symptoms generally appear within the first 24 hours and comprise of nausea, vomiting, anorexia, pallor, abdominal pain and liver damage may occur. Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage. Please inform your doctor if you notice any of these symptoms.

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.

Most serious side effects which immediate medical attention is required:

- **Very rare side effects** (may affect up to 1 in 10 000 people)
 - Serious skin reactions
 - Anaphylactic shock: sudden, severe allergic reaction with breathing difficulty (shortness of breath), swelling, light headedness, fast heartbeat, sweating and loss of consciousness.
 - Itchy rash (urticaria)
 - Rash

In the above cases, **stop your treatment immediately** and tell your doctor.

- **Rare side effects** (may affect up to 1 in 1 000 people)
 - Malaise.
 - Decreased blood pressure (hypotension).
 - Increased levels of liver enzymes indicates that the liver is under stress and may lead to liver problems.
 - **Very Rare side effects** (may affect up to 1 in 10 000 people)
 - Low level of blood platelets which can lead to bleeding and bruising.
 - Low levels of white blood cells.
 - Low levels of neutrophils, a type of white blood cell that fights infection.
- In the above cases, tell your doctor** because this may require additional blood test.
- Pain and burning sensation at the injection site even diffuse.
- **Not known** (frequency cannot be estimated from the available data)
 - Itching (pruritus)
 - Rapid heartbeat (tachycardia).
 - Reddening of the skin (flushing, erythema).
 - 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, pharmacist or nurse. 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

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

5. How to store Paracetamol 10 mg/mL solution for infusion

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

Do not refrigerate or freeze.

After opening the overwrapping: immediate use is recommended. Chemical and physical in-use stability has been demonstrated for 24 hours at 15 °C to 25 °C.

After dilution, chemical and physical in-use stability of the solution diluted in 0.9 % sodium chloride or 5 % glucose has been demonstrated for 2 hours (including the infusion time).

From a microbiological point of view, the product should be used immediately.

If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.

Before being administered, the product must be visually inspected. Do not use this medicine if you notice any particles.

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 to protect the environment.

6. Content of the pack and other information

What Paracetamol contains

- The active substance is paracetamol:

Each mL of solution for infusion contains 10 mg of paracetamol.

Each 10-mL bag of solution for infusion contains 100 mg paracetamol.

Each 50-mL bag of solution for infusion contains 500 mg paracetamol.

Each 100-mL bag of solution for infusion contains 1 000 mg paracetamol.

- The other ingredients are sodium acetate trihydrate, glacial acetic acid, sodium hydroxide 1N (for pH adjustment), water for injections.

What Paracetamol looks like and contents of the pack

This medicine is available as a solution for infusion.

10-mL overwrapped polyolefin bags equipped with a collection site are available in packs containing 1, 10, 15, 20 or 50 bags.

50-mL overwrapped polyolefin bags equipped with an infusion site are available in packs containing 1, 5, 10, 40, 45, 50 or 60 bags.

100-mL overwrapped polyolefin bags equipped with an infusion site are available in packs containing 1, 5, 10, 40, 45, 50 or 55 bags.

50-mL overwrapped polyolefin bags equipped with a collection site and an infusion site are available in packs containing 1, 5, 10, 40, 45, 50 or 60 bags.

100-mL overwrapped polyolefin bags equipped with a collection site and an infusion site available in packs containing 1, 5, 10, 40, 45, 50 or 55 bags.

Not all pack sizes may be marketed.

Marketing authorisation holder

LABORATOIRE AGUETTANT

1, RUE ALEXANDER FLEMING

69007 LYON

FRANCE

Manufacturer

AGUETTANT MOUVAUX

Rue Michel Raillard

59420 MOUVAUX

FRANCE

This medicinal product is authorised in the Member States of European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Belgium: Paracetamol Aguettant

France, Luxembourg, Germany: Paracetamol Aguettant

United Kingdom (Northern Ireland), Ireland: Paracetamol

This leaflet was last revised in 23/01/2025.

The following information is intended for healthcare professionals only:

Dosage

Dosing based on patient weight.

Patient weight	Dose per administration	Volume per administration	Maximum volume of Paracetamol 10 mg/mL solution for infusion per administration based on upper weight limits of group (mL)***	Maximum daily dose**
<u>10-mL bag</u>				
≤ 10 kg*	7.5 mg/kg	0.75 mL/kg	7.5 mL	30 mg/kg
<u>50-mL bag</u>				
> 10 kg to ≤ 33 kg	15 mg/kg	1.5 mL/kg	49.5 mL	60 mg/kg not exceeding 2 g
<u>100-mL bag</u>				
> 33 kg to ≤ 50 kg	15 mg/kg	1.5 mL/kg	75 mL	60 mg/kg not exceeding 3 g
> 50 kg with additional risk factors for hepatotoxicity	1 g	100 mL	100 mL	3 g
> 50 kg and no additional risk factors for hepatotoxicity	1 g	100 mL	100 mL	4 g

* **Pre-term newborn infants:** No safety and efficacy data are available for pre-term newborn infants (see section 5.2).

****Maximum daily dose:** The maximum daily dose as presented in the table above is for patients that are not receiving other paracetamol containing products and should be adjusted accordingly taking such products into account.

*****Patients weighing less will require smaller volumes.**

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

Do not administer more than 4 doses per 24 hours.

Special populations

- Case of reduced kidney function: in patients with a reduced kidney function, the minimum interval between each administration must be modified according to the following scheme:

Creatinine clearance	Administration interval
Clcr ≥ 50 mL/min	4 hours
Clcr 10-50 mL/min	6 hours
Clcr < 10 mL/min	8 hours

- Case of reduced hepatic function: in adult patients, in case of a reduced hepatic function, Gilbert disease, excessive alcohol consumption, chronic malnutrition (low hepatic glutathione reserves) or dehydration, the total dose of paracetamol per day should not exceed 3 g.

- Older patients: Dose adjustment is not required in the elderly. However, it should be taken into account that renal and/or hepatic insufficiency is more common in patients above 65 years of age.

Warnings

RISK OF MEDICATION ERRORS

Take care to avoid dosing errors due to confusion between **milligram (mg)** and **milliliter (mL)** which could result in accidental overdose and death.

Precautions

- The expiry date should be checked.
- Check that the bag has no leak, and discard any damaged or partially used bags, or, for 50- and 100-mL bags, those where the hanging hole is not opened.
- The overwrap should be removed from the bag after checking it is undamaged.
- Once opened, it should be used immediately.
- Before being administered, the product must be visually inspected to detect any particles. The solution must be clear and limpid.
- For single use only.
- Any unused solution must be discarded.
- This medicine can be diluted in 0.9 % sodium chloride or 5 % glucose solution up to one tenth (one volume of this medicine into nine volumes diluent). This solution diluted must be visually inspected again and should not be used if it is opalescent or contains visible particles or a precipitate.

For 50- and 100-mL bags:

Do not vent and do not connect in series with other infusions.

The protection should be removed from the infusion site.

The infusion set should be connected to the bag.

For 10-mL bag:

- 10-mL bag must not be hung as an infusion due to the small volume of the medicinal product to be administered in this population.
- The 10-mL bag must **not be used for direct infusion**. The volume to be administered should be withdrawn from the bag and should be given as is or diluted (in a volume from 1 to 9) in a 0.9 % sodium chloride solution or 5 % glucose solution and administered over 15 minutes.
- A 5- or 10-mL syringe should be used to measure the dose as appropriate for the weight of the child and the desired volume. However, this should never exceed 7.5 mL per dose.
- The user should be referred to the product information for dosing guidelines.