
PACKAGE LEAFLET: INFORMATION FOR THE USER

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 or pharmacist.
- 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 of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Paracetamol infusion is and what it is used for

This medicine is an analgesic (it relieves pain) and an antipyretic (it lowers fever).

It is indicated
- for the short-term treatment of moderate pain, especially following surgery, and
- for the short-term treatment of fever.

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

Do not use Paracetamol infusion
- if you are **allergic** (hypersensitive) **to Paracetamol** or any of the other ingredients of Paracetamol infusion (listed in section 6).
- if you are **allergic** (hypersensitive) **to propacetamol** (another pain killer and a precursor of Paracetamol).
- if you suffer from a **severe liver disease**.

Warnings and precautions
Talk to your doctor before using Paracetamol infusion .

Take special care with Paracetamol infusion
- if you suffer from a **liver or kidney disease**, or from **alcohol abuse**.
- if you suffer from a inherited liver function disorder called **Meulengracht Gilbert's syndrome**.
- if you suffer from **glucose-6-phosphate dehydrogenase deficiency.**
- if you are taking **other medicines containing Paracetamol** .
- if you suffer from a **severe lack of nutrition** (malnutrition) or get parenteral nutrition
- if you suffer from exsiccation
- talk to your doctor or pharmacist if you are taking or will be taking flucloxacillin. There is a risk of blood and fluid abnormality (high anion gap metabolic acidosis) which occurs when

there is an increase in plasma acidity, when Paracetamol is used concomitantly with flucloxacillin, particularly in certain groups of patients at risk, *e.g.* patients with severe renal impairment, sepsis or malnutrition, especially if the maximum daily doses of Paracetamol are used. High anion gap metabolic acidosis is a serious disease that must have urgent treatment.

Inform your doctor before treatment if any of the above mentioned conditions apply to you.

You should switch to taking pain killing tablets or syrup instead of Paracetamol infusion as soon as is possible.

Other medicines and Paracetamol infusion
You should not take **other medicines containing Paracetamol** if you are taking Paracetamol infusion , in order not to exceed the recommended daily dose (see following section). Inform your doctor if you are taking other medicines containing Paracetamol.

If you are using **probenecid** (a medicine used for the treatment of gout) your doctor should consider reducing the dose of Paracetamol you need, as probenecid increases the levels of Paracetamol in your blood.

Salicylamide (another pain killer) may increase the levels of Paracetamol in your blood and may therefore increase the risk of its toxic effects.

Rifampicin, isoniazid (antibiotics), **barbiturates** (sedatives), **tricyclic antidepressants** and **medicines to treat epileptic fits** (antiepileptics such as carbamazepine, phenytoin, phenobarbital, primidone) may reduce the analgesic and antipyretic effects of Paracetamol and may increase as well as **alcohol** its liver toxic effects.

Taking Paracetamol and **chloramphenicol** (an antibiotic) together may prolong the action of the latter one.

Please inform your doctor or pharmacist if you taking **oral contraceptives** as these may shorten the action of Paracetamol.

Taking Paracetamol and **zidovudine** (a medicine used to treat HIV) together may lead to an increased risk of a reduction in the number of certain white blood cells (neutropenia). This increases your risk of getting infections.

Please inform your doctor or pharmacist if you are taking **oral anticoagulants** (substances that slow blood clotting). More check-ups to assess the effect of the anticoagulant might be needed.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

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

Pregnancy
If necessary, Paracetamol infusion 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.
Breast-feeding
Paracetamol infusion may be used during breast-feeding.

Driving and using machines
Paracetamol infusion has no influence on the ability to drive or use machines.

3. How to use Paracetamol infusion

This product is for intravenous use.

Your doctor will administer Paracetamol infusion to you. It is administered by drip (infusion).

The 100 ml vial or bag is restricted to adults, adolescents and children weighing more than 33 kg (approximately 11 years old).

The 10 ml ampoule and the 50 ml vial or bag is restricted to term newborn infants, infants, toddlers and children weighing less than 33 kg.

Your doctor should closely monitor you before the end of the infusion, in order to avoid air entering your vein.

Dosage

Dosing based on patient weight (please see the dosing table here below):

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****
≤ 10 kg*	7.5 mg/kg	0.75 mL/kg	7.5 mL	30 mg/kg
> 10 kg to ≤ 33 kg	15 mg/kg	1.5 mL/kg	49.5 mL	60 mg/kg, not exceeding 2 g
> 33 kg to ≤ 50 kg	15 mg/kg	1.5 mL/kg	75 mL	60 mg/kg, not exceeding 3 g
> 50 kg and 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
****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 in patients with normal renal function.**
- **The minimum interval between each administration in patients with severe renal insufficiency must be at least 6 hours.**
- **The minimum interval between each administration in patients requiring haemodialysis must be at least 8 hours.**
- **The maximum daily dose must not exceed 3 g in adult patients with chronic or compensated active hepatic disease, hepatocellular insufficiency, chronic alcoholism, chronic malnutrition (low reserves of hepatic glutathione), dehydration, Meulengracht Gilbert Syndrome, weighing less than 50 kg.**
- **No more than 4 doses to be given in 24 hours.**

How Paracetamol infusion infusion is given

RISK OF MEDICATION ERRORS Take care to avoid dosing errors due to confusion between milligram (mg) and millilitre (mL), which could result in accidental overdose and death.

Paracetamol infusion solution is administered as an infusion (via a drip) into your vein over 15 minutes.
An interval of at least 4 hours must be left between administrations**.**

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

If you use more Paracetamol infusion than you should
If you have used more Paracetamol infusion than you should talk to your doctor or pharmacist immediately.

In overdose cases, symptoms generally appear within the first 24 hours and comprise: nausea, vomiting, loss of appetite, paleness and belly ache. Immediate medical advice should be sought in the event of overdosage, because of the risk of irreversible liver damage.

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

4. Possible side effects

Like all medicines, Paracetamol infusion can cause side effects, although not everybody gets them.

Common (may affect up to 1 in 10 people)
pain and burning sensation at the injection site.
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). Should this occur, inform your doctor as regular blood tests may be required.
- Low blood pressure (hypotension)
- Feeling unwell (malaise)

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

- Reduced number of certain blood cells (platelets, certain white blood cells), possibly leading to bleeding from the nose or gums and an increased risk of infections. Should these occur, inform your doctor, as regular blood tests may be required.
- Allergic reactions ranging from simple skin rash 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, wheezing or difficulty breathing, temporary narrowing of the airways into the lungs (bronchospasm).
  If you think that Paracetamol infusion infusion is causing an allergic reaction, tell your doctor immediately.
- Very rare cases of serious skin reactions have been reported.
- Very rare cases of blood and fluid abnormality (high anion gap metabolic acidosis) which occurs when there is an increase in plasma acidity, when Paracetamol is used concomitantly with flucloxacillin, generally in the presence of risk factors (see section 2).

Isolated reports (it is not known how common these are)

- Fast heart beat (tachycardia)
- Redness of the skin, flush, itching

Effects on laboratory tests

Treatment with Paracetamol infusion may alter the results of some laboratory tests for uric acid, as well as of the test for blood glucose.

If any of the side effects gets serious or if you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

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:

For the UK : via the Yellow Card Scheme at : www.mhra.gov.uk/yellowcard

For Ireland: Reports may be made by following the links to the online reporting option accessible from the HPRA homepage, or by completing the download report form also accessible from the HPRA website, which may be completed manually and submitted to the HPRA via freepost, to the following address:

Pharmacovigilance Section

Health Products Regulatory Authority

Earlsfort Centre

Earlsfort Terrace

Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

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

5. How To Store Paracetamol infusion

Keep out of the sight and reach of children.

Do not use Paracetamol infusion infusion after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of the month.

Do not refrigerate or freeze.

Before administration, the product should be inspected visually.
Do not use Paracetamol infusion if you notice any particles in the solution or discolouration other than slightly yellowish.

Your doctor or the hospital staff will normally store Paracetamol infusion and they are responsible for the quality of the product when it has been opened and if it is not used immediately. However, if not used immediately it should normally not be stored longer than 24 hours. After dilution, the solution should be stored no longer than 6 hours (including the infusion time). They are also responsible for disposing of any unused Paracetamol infusion correctly.

Medicines should not be disposed of via wastewater or household waste. Your doctor, nurse or pharmacist will dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Paracetamol infusion contains
- The active substance is Paracetamol infusion infusion. One ml contains 10 mg Paracetamol.
- Each 10 ml ampoule contains 100 mg Paracetamol.
- Each 50 ml vial or bag contains 500 mg Paracetamol infusion.
- Each 100 ml vial or bag contains 1,000 mg Paracetamol infusion.
- The other ingredients are cysteine, mannitol (E421), water for injections.

What Paracetamol infusion looks like and contents of the pack
Paracetamol 10 mg/ml solution for infusion is a clear and slightly yellowish solution for infusion.
Paracetamol 10 mg/ml solution for infusion is available in 10 ml glass ampoules and 50 ml or 100 ml glass vials closed with stoppers and aluminium/plastic flip-off caps and 50 ml and 100 ml bags closed with stoppers and a plastic tamper-evident covers.

Pack sizes:

Ampoules:
10 ampoules

Vials:
1 vial
10 vials
12 vials
20 vials.

Bags:
20 bags
50 bags
60 bags

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
For UK
Fresenius Kabi Ltd, Cestrian Court, Eastgate Way, Manor Park, Runcorn,
Cheshire,
WA7 1NT, UK

For IRL
Fresenius Kabi Deutschland GmbH
Else-Kroener Strasse 1,
Bad Homburg
v.d.H 61352,
Germany

Manufacturer
Fresenius Kabi Deutschland GmbH, Freseniusstraβe,61169 Friedberg, Germany

Or

Fresenius Kabi Austria GmbH,
Hafnerstraβe 36,
8055 Graz,
Austria

Or
Fresenius Kabi France
6 rue du Rempart – 27400 Louviers – France

Or
Fresenius Kabi Norge AS
Svinesundveien 80-NO-1753 Halden, Norway

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Paracetamol Kabi 10 mg/ml Infusionslösung
Belgium	Paracetamol Fresenius Kabi 10 mg/ml oplossing voor infusie
Bulgaria	Парацетамол Каби 10 mg/ml инфузионен разтвор
Cyprus	Paracetamol /Kabi
Czech Republic	Paracetamol Kabi
Denmark	Paracetamol “Fresenius Kabi”
Estonia	Paracetamol Kabi 10 mg/ml
Finland	Paracetamol Fresenius Kabi
Germany	Paracetamol Kabi 10 mg/ml Infusionslösung
Greece	Paracetamol /Kabi

Hungary	Paracetamol Kabi 10 mg/ml
Ireland	Paracetamol 10 mg/ml solution for infusion
Italy	Paracetamolo Kabi 10 mg/ml
Latvia	Paracetamol Kabi 10 mg/ml šķīdums infūzijām
Lithuania	Paracetamol Kabi 10 mg/ml infuzinis tirpalas
Luxembourg	Paracetamol Kabi 10 mg/ml Infusionslösung
Norway	Paracetamol "Fresenius Kabi" 10 mg/ml infusjons-væske, oppløsning
Poland	Paracetamol Kabi
Portugal	Paracetamol Kabi
Romania	Paracetamol Kabi 10 mg/ml, soluţie perfuzabilă
Slovakia	Paracetamol Kabi 10 mg/ml
Slovenia	Paracetamol Kabi 10 mg/ml raztopina za infundiranje
Spain	Paracetamol Kabi 10 mg/ml solución para perfusión
Sweden	Paracetamol Fresenius Kabi
The Netherlands	Paracetamol Fresenius Kabi 10 mg/ml oplossing voor infusie
UK	Paracetamol 10 mg/ml solution for infusion

This leaflet was last revised in May 2020.

The following information is intended for healthcare professionals only:

Handling
For single use only. Any unused solution should be discarded.

Before administration, the product should be visually inspected for any particulate matter and/or discolouration.

The 100 ml vial or bag is restricted to adults, adolescents and children weighing more than 33 kg.

The 10 ml ampoule and the 50 ml vial or bag is restricted to term newborn infants, infants, toddlers and children weighing less than 33 kg.
As for all solutions for infusion presented in vials or bags, it should be remembered that close monitoring is needed notably at the end of the infusion, regardless of infusion route. This monitoring at the end of the infusion applies particularly for central route infusions, in order to avoid air embolism.

Compatibility
Paracetamol 10 mg/ml solution for infusion can be diluted in sodium chloride 9 mg/ml (0.9%) solution or 50 mg/ml glucose (5%) solution up to one tenth (one volume Paracetamol 10 mg/ml solution for infusion into nine volumes diluent). In this case, the diluted solution should be used within 6 hours following its preparation (infusion time included).

The diluted solution should be visually inspected and should not be used in the presence of opalescence, visible particulate matter or precipitate.

Disposal
Any unused product or waste material should be disposed of in accordance with local requirements.