

Package Leaflet: Information for the user

Paracetamol 10 mg/ml solution for infusion

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.
- 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.

What is in this leaflet:

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

The name of your medicine is “Paracetamol 10 mg/ml solution for infusion” but it will be referred to as “Paracetamol” throughout this leaflet.

1. What Paracetamol is and what it is used for

This medicine contains paracetamol, which is an analgesic (a painkiller) and an antipyretic (it reduces fever).

It is used for

- short-term treatment of **moderate pain**, especially following surgery.
- short-term treatment of **fever**.

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

The 50 ml vial is adapted to term newborn infants, infants, toddlers and children weighing less than 33 kg.

2. What you need to know before you are given Paracetamol

You will not be given Paracetamol

- if you are **allergic** to paracetamol or to any of the other ingredients of this medicine (listed in section 6)
- if you are **allergic** to propacetamol (this is another painkiller that the body converts to paracetamol)
- if you have **severe liver disease**.

Warnings and precautions

Talk to your doctor before you receive Paracetamol if any of these apply to you:

- if you could take painkillers **by mouth** (orally) since that is the recommended administration route
- if you have reduced **liver** or **kidney function**, or if you **drink too much alcohol**
- in cases of **nutrition problems** (underfeeding, malnutrition) or **dehydration**
- if you have a genetic disorder of the enzyme glucose-6-phosphate-dehydrogenase, which may lead to a **blood disease** known as haemolytic anaemia.

Other medicines and Paracetamol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, especially the following:

- other medicines containing **paracetamol** or **propacetamol** (so that you do not take more than the recommended daily dose)
- a medicine called **probenecid** (used to treat gout)
- an anti-inflammatory medicine call **salicylamide**
- medicines that activate liver enzymes
- any **blood thinning medicines** (anticoagulants) taken by mouth
- a medicine called **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 renal 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.

Paracetamol with alcohol

You should limit the use of alcohol during treatment with this medicine.

Pregnancy and breastfeeding

If necessary, Paracetamol can be used during pregnancy. You should be given the lowest possible dose that reduces your pain and/or your fever, and for the shortest time possible. Tell your doctor or nurse if the pain and/or fever are not reduced or if you need to be given the medicine more often.

Paracetamol may be used during breast-feeding.

Driving and using machines

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

Paracetamol contains sodium

This medicine contains less than 1 mmol (23 mg) sodium, which means it is essentially sodium free.

3. How you will be given Paracetamol

How medicine will be given

This medicine will be given to you by a healthcare professional through a drip (infusion) into a vein. This usually takes about 15 minutes. You will be closely monitored during and especially towards the end of the infusion.

How much will you be given

Your doctor will calculate the dose based on your weight and general condition.

If you are given more Paracetamol than you should

Talk to a doctor at once if you are given too much of this medicine even if you feel well. This is because too much paracetamol can cause serious liver damage.

Overdose is unlikely as a healthcare professional will give you this medicine. Your doctor will make sure not to give you doses higher than the recommended dose in your case. However, in overdose cases, symptoms generally appear within the first 24 hours and comprise: nausea, vomiting, anorexia, pallor, abdominal pain and a risk of liver injury. If you think you have received more Paracetamol than you should, talk to your doctor immediately.

4. Possible side effects

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

Serious side effects

If you notice any of the following side effects, **tell your doctor or nurse immediately:**

- **allergic reactions** of varying severity, ranging from skin reactions (e.g. nettle rash) to allergic shock
- **serious skin reactions**
- abnormally low levels of some types of blood cells (platelets, white cells), which may lead to **bleeding from the nose or gums.**

Other side effects:

If any of these side effects become troublesome, please speak to your doctor or nurse.

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)

- abnormally high levels of liver enzymes found during blood tests
- drop in blood pressure
- malaise (generally feeling unwell)

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

- other changes in laboratory test results have been observed which have necessitated regular blood checks: abnormally low levels of some types of blood cells (platelets, white cells), possibly leading to bleeding from the nose or gums.
- 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).

Not known (frequency cannot be estimated from the available data)

- redness of the skin, flushing or itching
- abnormally rapid beating of the heart

Reporting of side effects

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Paracetamol

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.

Store below 30°C.

Keep the vial in the outer carton in order to protect from light.

Do not refrigerate or freeze.

6. Contents of the pack and other information

What Paracetamol contains:

Each 1 ml contains 10 mg paracetamol.

Each 50 ml vial contains 500 mg paracetamol.

Each 100 ml vial contains 1000 mg paracetamol.

The other ingredients are mannitol, disodium phosphate dihydrate, hydrochloric acid, sodium hydroxide, cysteine hydrochloride, water for injections.

What Paracetamol looks like and contents of the pack

Your medicine is a clear, slightly yellow solution, supplied in 50 ml and 100 ml glass vials.

Pack sizes: 1, 5 or 10 vials

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Istituto Biochimico Italiano G. Lorenzini S.p.A.

Via Fossignano 2

Aprilia (LT)

Italy

Manufacturer

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Zona Industriale Tito Scalo,

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Italy

This leaflet was last revised in 11/2024.

The following information is intended for healthcare professionals only:

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

The 50 ml vial is adapted to term newborn infants, infants, toddlers and children weighing less than 33 kg.

Posology

Dosing based on patient weight - see the dosing table below.

Patient weight	Dose per administration	Volume per administration	Maximum volume 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 with additional risk factors for hepatotoxicity	1 g	100 ml	100 ml	3 g
> 50 kg and no additional risk	1 g	100 ml	100 ml	4 g

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

** Patients weighing less will require smaller volumes.

*** 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.

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

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

No more than 4 doses to be given in 24 hours.

Elderly

Dose adjustment is not required in elderly people (see section 5.2).

Severe renal insufficiency:

It is recommended, when giving paracetamol to patients with severe renal impairment (creatinine clearance ≤ 30 ml/min), to reduce the dose and increase the minimum interval between each administration to 6 hours (See section 5.2).

Adults with hepatocellular insufficiency, chronic alcoholism, chronic malnutrition (low reserves of hepatic glutathione), dehydration:

The maximum daily dose must not exceed 3 g (see section 4.4).

Method of administration

The paracetamol solution is administered as a 15-minute intravenous infusion.

Paracetamol can also be diluted in 0.9% sodium chloride solution or 5% glucose solution up to one tenth (one volume Paracetamol into nine volumes diluent). In this case, use the diluted solution within the hour following its preparation (infusion time included).

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

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

As for all solutions for infusion presented in containers with air space inside, it should be remembered that close monitoring is needed notably at the end of the infusion, regardless of administration route. This monitoring at the end of the infusion applies particularly for central route infusions, in order to avoid air embolism.

Dosing guide

Patient weight (kg)	Volume per administration (ml)	Dose per administration (mg)
3	2.25	22.5
4	3.0	30.0
5	3.75	37.5
6	4.5	45.0
7	5.25	52.5

8	6.0	60.0
9	6.75	67.5
10	7.5	75.0
20	30.0	300.0
30	45.0	450.0

Patient weight (kg)	Volume per administration (ml)	Dose per administration (mg)
33	49.5	495.0
34	51.0	510.0
36	54.0	540.0
38	57.0	570.0
40	60.0	600.0
42	63.0	630.0
44	66.0	660.0
46	69.0	690.0
48	72.0	720.0
50	75.0	750.0
>50	100.0	1000.0