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.
- 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

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

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

2. What you need to know before you use Paracetamol

Do not use 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 (hypersensitive) to propacetamol (another analgesic, being converted to paracetamol in your body)
- if you suffer from a severe liver disease.

Warnings and precautions
Talk to your doctor before you receive Paracetamol

Take special care with Paracetamol
- if you suffer from liver or severe kidney disease, or from chronic alcohol abuse
- if you are taking other medicines containing paracetamol. In this case your doctor will adjust your dose
- in cases of nutrition problems (states of underfeeding, malnutrition) or dehydration
- if you suffer from a genetically caused disorder of the enzyme glucose-6-phosphatedehydrogenase (favism)

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

Prolonged or frequent use of paracetamol is discouraged. It is recommended that this medicine should only be used until you are able to take pain killers by mouth again.

Your doctor will assure not to give you doses higher than recommended. This may lead to severe liver damage.

Other medicines and Paracetamol

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

This is especially important if you are taking:
- a medicine called *probenecid* (used to treat gout): reduction of the paracetamol dose may be required.
- painkillers containing *salicylamide*: adjustment of the dose may be required.
- *medicines that activate liver enzymes*: strict control of the paracetamol dose is required in order to avoid liver damage.
- any *blood thinning medicines* (anticoagulants): a more careful control of the effect of these medicines may be necessary.
- 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.

This medicine contains paracetamol and this must be taken into account if *other medicines containing paracetamol or propacetamol* are taken, in order to avoid overdose (see section 3).

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 for advice before taking this medicine.

- Pregnancy

If necessary, Paracetamol 10 mg/ml solution for 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 may be used during breast-feeding.

Paracetamol contains Sodium

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

3. How to use Paracetamol

The recommended dose is:

The dose will be individually adjusted by your doctor, based on your weight and general condition.

Method of administration

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

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

If you are given more Paracetamol than you should

Overdose is unlikely as you will be given this medicine by a healthcare professional.

Your doctor will assure not to give you doses higher than recommended.

In overdose cases, symptoms generally appear within the first 24 hours and comprise: feeling sick, being sick, anorexia (loss of appetite), pasty skin and abdominal pain. These symptoms could reflect liver injury.

If you think you may have been given an overdose, tell a doctor immediately. Immediate medical advice should be sought in the event of an overdose, even if you feel well, to avoid risk of serious and irreversible liver damage. If required an antidote may be given to you.

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

4. Possible side effects

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

The following side effects may be serious. If any of them occur, stop Paracetamol and seek medical attention immediately:
Very rare (may affect up to 1 in 10 000 people)
- allergic reactions of varying severity, ranging from skin reactions like nettle rash to allergic shock
- serious skin reactions
- abnormally low levels of some types of blood cells (platelets, white cells) can occur

Other side effects include:

Rare (may affect up to 1 in 1 000 people)
- changes in laboratory test results: abnormally high levels of liver enzymes found during blood checks
- drop in blood pressure
- malaise

Not known (frequency cannot be estimated from the available data)
- redness of the skin, flushing or itching
- abnormally rapid beating of the heart

Frequent side effects at injection site have been reported during clinical trials (pain and burning sensation).

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland:
HPRA Pharmacovigilance, Website: www.hpra.ie

Malta:
ADR Reporting Website:
www.medicinesauthority.gov.mt/adrportal

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.

Do not store above 30 °C.

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

6. Contents of the pack and other information

What Paracetamol contains:

The active substance is paracetamol.
One ml contains 10 mg paracetamol.
Each 10 ml ampoule contains 100 mg paracetamol.
Each 50 ml bottle contains 500 mg paracetamol.
Each 100 ml bottle contains 1000 mg paracetamol.

The other ingredients are:
Mannitol, sodium citrate dihydrate, acetic acid glacial (for pH adjustment), water for injections.

What Paracetamol solution for infusion looks like and contents of the pack

Paracetamol solution for infusion is a clear and colourless to slightly pinkish-orangish solution. Perception may vary.

Paracetamol is supplied in plastic bottles of 50 ml of 100 ml or a plastic ampoule of 10 ml.

Pack sizes: 20 x 10 ml, 10 × 50 ml, 10 × 100 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen, Germany

Postal address:
34209 Melsungen, Germany

Phone: +49/5661/71-0
Fax: +49/5661/71-4567

Manufacturer:
B. Braun Medical SA
Carretera de Terrassa 121
08191 Rubí (Barcelona)
Spain

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

Austria, Germany	Paracetamol B. Braun 10 mg/ml Infusionslösung
Belgium	Paracetamol B. Braun 10 mg/ml solution for infusion, oplossing voor infusie, Infusionslösung
Bulgaria, Czech Republic, Estonia, Finland, France, Italy, Luxembourg, Portugal, Slovakia, Sweden, The Netherlands	Paracetamol B. Braun 10 mg/ml
Ireland, United Kingdom (Northern Ireland), Malta	Paracetamol 10 mg/ml solution for infusion
Latvia	Paracetamol B. Braun 10 mg/ml šķīdums infūzijām
Lithuania	Paracetamol B. Braun 10 mg/ml infuzinis tirpalas
Denmark, Poland, Norway	Paracetamol B. Braun
Romania	Paracetamol B. Braun 10 mg/ml solutie perfuzabila
Slovenia	Paracetamol B. Braun 10 mg/ml raztopina za infundiranje
Spain	Paracetamol B. Braun 10 mg/ml solución para perfusión EFG

This leaflet was last revised in 07/2022.

Other sources of information

Ireland:
Detailed information on this medicine is available on the website of the Health Products Regulatory Authority (HPRA): www.hpra.ie

Malta:
Detailed information on this medicine is available on the website of the Malta Medicines Authority: www.medicinesauthority.gov.mt

---

The following information is intended for healthcare professionals only:

Posology

- The **polyethylene bottle containing 100 ml** is restricted to adults, adolescents and children weighing more than 33 kg .
- The **polyethylene bottle containing 50 ml** is restricted to toddlers and children weighing more than 10 kg and up to 33 kg.
- The **polyethylene ampoule containing 10 ml** is restricted to term newborn infants, infants and toddlers weighing up to 10 kg.

The volume to be administered must not exceed the determined dose. If applicable the desired volume must be diluted in a suitable solution for infusion prior to administration (see below 'Method of administration and dilution') or a syringe driver must be used.

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.

Prolonged or frequent use is discouraged. It is recommended that a suitable analgesic oral treatment will be used as soon as this route of administration is possible.

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

10 ml ampoule				
Patient weight	**Dose per administration**	**Volume per administration**	**Maximum volume of Paracetamol (10 mg/ml) 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

50 ml bottle				
Patient weight	**Dose per administration**	**Volume per administration**	**Maximum volume of Paracetamol (10 mg/ml) per administration based on upper weight limits of group (ml)*** **	**Maximum daily dose****
> 10 kg to ≤ 33 kg	15 mg/kg	1.5 ml/kg	49.5 ml	60 mg/kg not exceeding 2 g
100 ml bottle				
Patient weight	**Dose (per administration)**	**Volume per administration**	**Maximum volume of Paracetamol (10 mg/ml) per administration based on upper weight limits of group (ml)*** **	**Maximum daily dose****
> 33 kg and ≤ 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

*Preterm newborn infants:
No safety and efficacy data are available for premature 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.
The minimum interval between each administration in patients with severe renal insufficiency must be at least 6 hours.

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

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.

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 'warnings and precautions').

Method of administration and dilution
Paracetamol can also be diluted in sodium chloride 9 mg/ml (0.9 %) solution for infusion or glucose 50 mg/ml (5 %) solution for infusion or a combination of both solutions up to one tenth (one volume Paracetamol into nine volumes diluent).

For single use only. The medicine should be used immediately after opening. Any unused solution should be discarded.

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.

Shelf life after first opening
The infusion should commence immediately after connecting the container to the giving set.

Shelf life after dilution
Chemical and physical in use stability (including infusion time) has been demonstrated for 48 hours at 23 °C.

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 administration, the medicine should be visually inspected for any particulate matter and discolouration. Only to be used if solution is clear, colourless or slightly pinkish-orangish (perception may vary) and the container and its closure are undamaged.