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 contains the active substance paracetamol, and it is an analgesic (it relieves pain) and an antipyretic (it lowers fever).

Newborn infants, infants, toddlers and children (less than or equal to 33 kg)

Use 50 ml fill vial.

Adults, adolescents and children (above 33 kg)

Use 100 ml fill vial.

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

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 to propacetamol hydrochloride. This is another painkiller that the body converts to paracetamol.
- if you have a severe liver disease.

Warnings and precautions

Talk to your doctor or pharmacist before using Paracetamol, if any of these apply to you:

- if you could take painkillers through the mouth (orally) instead, since that is the recommended administration route.
- if you have reduced liver or kidney function, or if you drink too much alcohol.
- if you are taking other medicines that have paracetamol in them.
- in cases of malnutrition or dehydration.
- If you have a glucose-6-phosphate dehydrogenase deficiency. This is a disease of the blood.

Other medicines and Paracetamol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Paracetamol can affect and be affected by other medicines:

- other medicines that contain paracetamol or propacetamol, so that you do not take more than the recommended daily dose (see section 3 “How to use Paracetamol”).
- probenecid: a lower dose of paracetamol may be needed.
- salicylamide, an anti-inflammatory drug.
- anticoagulants taken by mouth. It may be necessary to control the effect of the anticoagulant.
- medicines that activate liver enzymes: strict control of the paracetamol dose is required in order to avoid liver damage.
- flucloxacillin (antiobitic), 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

Limit the use of alcohol during treatment with this medicine.

Pregnancy and breast-feeding

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

Pregnancy

If necessary, Paracetamol can be given during pregnancy. You will be given the lowest possible dose that reduces your pain or fever. Contact your doctor, if the pain or fever are not reduced.

Breast-feeding

You can have Paracetamol if you are breast-feeding.

Driving and using machines

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

Paracetamol contains sodium

This medicine contains less than 1 mmol sodium (23mg) per vial, that is to say essentially "sodium free".

3. How to use Paracetamol

For intravenous use.

A healthcare professional will give you paracetamol by infusion into one of your veins.

Your doctor will adjust your dose to suit you individually. Dosing is based on weight of the patient and general health.

Newborn infants, infants, toddlers and children (less than or equal to 33 kg)

Use 50 ml fill vial. See dosing table below for volume per body weight.

Adults, adolescents and children (above 33 kg)

Use 100 ml fill vial. See dosing table below for volume per body weight.

Dosage

For recommended dose, see the table below.

- 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.
- The medicine is given into a vein over 15 minutes.
- Before administration, the product is visually inspected by health care professionals. Paracetamol must not be used if any visual particulate matter and discoloration is present. These are signs of deterioration.

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
> 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 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.
****Patients weighing less will require smaller volumes.**
***** Maximum daily dose:** The maximum daily dose of paracetamol as presented in the table above is for patients that are not receiving other medicines that contain paracetamol. This dose must be adjusted accordingly if the patient is taking such medicines.

Renal impairment:
In patients with renal impairment, the interval between each administration will be adjusted.

Hepatic insufficiency
In patients with chronic or compensated active hepatic disease, hepatocellular insufficiency, chronic alcoholism, chronic malnutrition (low reserves of hepatic glutathione), dehydration, Gilbert's syndrome, weighing less than 50 kg: The maximum daily dose must not exceed 3 g.

The paracetamol solution is administered in intravenous infusion over 15 minutes.
If you think that the effect of this medicine is too strong or too weak, talk to your doctor.

If you receive more Paracetamol than you should
Overdose is unlikely as a health care professional will give you this medicine. Your doctor will make sure not to give you doses higher than the recommended dose in your case.

An overdose of Paracetamol is potentially lethal due to irreversible liver damage. ***There is a risk of serious liver damage even if you feel well.***

In order to avoid liver damage it is essential to get medical treatment ***as early as possible****. The shorter the interval between infusion and initiation of treatment with antidote (as few hours as possible), the greater the likelihood that hepatic injury can be prevented.*

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. Talk to a doctor at once if you or your child receives too much of this medicine even if you or your child seem to feel well. This is because too much paracetamol can cause delayed, serious liver damage.
If you have any 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.

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

The following may occur:

- a malaise
- a drop in blood pressure
- changes in laboratory test results: abnormally high levels of hepatic enzymes found during blood checks. Should this occur, inform your doctor as regular blood checks may be required later.

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

The following may occur:

- a serious skin rash or allergic reaction may occur. Stop the treatment immediately and inform your doctor;
- 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;
- very rare cases of serious skin reactions have been reported.

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

- Cases of redness of the skin, flushing, itching and abnormally rapid beating of the heart have been reported.
- Cases of pain and burning sensation at injection site have been reported.

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 (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

United Kingdom:

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store Paracetamol

Keep this medicine out of the sight and reach of children.

You should not be given this medicine after the expiry date which is stated on the carton and vial label after EXP. The expiry date refers to the last day of that month.

Do not refrigerate or freeze.

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

6. Contents of the pack and other information

What Paracetamol contains

The active substance is paracetamol.

1 ml contains 10 mg paracetamol.

Each vial of 50 ml contains 500 mg paracetamol

Each vial of 100 ml contains 1000 mg paracetamol

The other ingredients are mannitol (E421), cysteine hydrochloride monohydrate (E920), disodium phosphate (E339), sodium hydroxide (for pH adjustment) (E524), hydrochloric acid hydrochloric acid, concentrated (for pH adjustment) (E507), water for injections.

What Paracetamol looks like and contents of the pack

Paracetamol is a clear, colourless to slightly yellowish solution and free from visible particles.

This medicine is available in glass vials, with stoppers and red (for 50 ml fill volume) or blue (for 100 ml fill volume) aluminium flip-off caps.

Paracetamol is supplied in pack of 25 vials.

Marketing Authorisation Holder

Ireland:

Baxter Holding B.V.

Kobaltweg 49,

3542CE Utrecht,

Netherlands

United Kingdom:
Baxter Healthcare Limited
Caxton Way,
Thetford,
Norfolk,
IP24 3SE,
United Kingdom

Manufacturer
Bieffe Medital S.P.A
Via Nuova Provinciale
23034-Grosotto (SO), Italy

This medicinal product is authorised in the Member States of the EEA under the following names:
Austria and Germany: Paracetamol Baxter 10 mg/ml Infusionslösung
Belgium, France, Luxemburg: Paracetamol Baxter 10 mg/ml solution pour perfusion
Greece and Cyprus: Paracetamol/Baxter 10 mg/ml Διάλυμα για έγχυση
Denmark: Paracetamol Baxter 10 mg/ml infusionsvæske, opløsning
Finland: Paracetamol Baxter 10 mg/ml infuusioneste, liuos
Ireland and United Kingdom: Paracetamol 10 mg/ml Solution for Infusion
Italy: Paracetamolo Baxter
Netherlands: Paracetamol Baxter 10 mg/ml oplossing voor infusie
Portugal and Norway: Paracetamol Baxter
Spain: Paracetamol Baxter 10 mg/ml solución para perfusión EFG
Sweden: Paracetamol Baxter 10 mg/ml infusionsvätska, lösning

This leaflet was last revised in 11/2022

----------**TEAR-OFF SECTION BELOW** ----------
The following information is intended for healthcare professionals only:

INFORMATION FOR HEALTH PROFESSIONALS

A summary of the dosage, dilution, administration and storage details for Paracetamol 10 mg/ml, solution for infusion. See the Summary of Product Characteristics for full prescribing information.

Intravenous use.

Newborn infants, infants, toddlers and children (less than or equal to 33 kg)

Use 50 ml fill vial.

Adults, adolescents and children (above 33 kg)

Use 100 ml fill vial.

As for all solutions for infusion presented in glass vials, 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 perfusion applies particularly for central route infusions, in order to avoid air embolism.

Dosage

Information before preparation of the dose

- 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.
- The paracetamol solution is administered in intravenous infusion over 15 minutes (for more details, see section "Method of administration" below the dosing table).
- The diluted solution should be visually inspected and must not be used if opalescence, visible particulate matter or precipitate are found.

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 (see SmPC section 4.2).

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) per administration based on upper weight limits of group (mL)****	**Maximum Daily Dose *****
≤10 kg *	7.5 mg/kg	0.75 mL/kg	7.5mL	30 mg/kg
> 10 kg to ≤ 33 kg	15 mg/kg	1.5 mL/kg	49.5mL	60 mg/kg not exceeding 2g
> 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.

****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.

Renal impairment:

In patients with renal impairment, the minimum interval between each administration should be modified according to the following schedule:

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

Hepatic insufficiency

In patients with chronic or compensated active hepatic disease, hepatocellular insufficiency, chronic alcoholism, chronic malnutrition (low reserves of hepatic glutathione), dehydration, Gilbert's syndrome, weighing less than 50 kg: The maximum daily dose must not exceed 3 g.

Method of administration

Patients weighing ≤ 10 kg:

- The glass vial of Paracetamol should not be hung as an infusion due to the small volume of the medicinal product to be administered in this population.
- The volume to be administered should be withdrawn from the vial and could be administered undiluted or diluted in a 0.9% sodium chloride solution or 5% glucose solution up to one tenth (one volume Paracetamol into nine volumes diluent) 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. The volume administered to this weight group should never exceed 7.5 ml per dose.
- The user should refer to the dosage recommendations in the summary of product characteristics.

To remove solution, use a 0.8 mm needle (21-gauge needle) must be used and the stopper vertically perforated at the spot specifically indicated. For single use only. Any unused solution should be discarded.

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

Shelf life after dilution

Chemical and physical in-use stability in the solutions has been demonstrated for 48 hours at 20-25 ° 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 and would normally not be longer than 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.