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). The medicine is restricted to adults, adolescents and children weighing more than 33 kg.

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. This medicine 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, ask your doctor or pharmacist for advice before receiving this medicine.

Pregnancy

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

Breast-feeding

You can have this medicine if you are breast-feeding.

Driving and using machines

This medicine has no influence on the ability to drive or use machines.

Paracetamol contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per bag, 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.

The medicine is restricted to adults, adolescents and children weighing more than 33 kg.

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.

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 to ≤50 kg	15 mg/kg	1.5 mL/kg	75 mL	60 mg/kg not exceeding 3g
>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

****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 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 this medicine 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 cases (**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. Should this occur, inform your doctor.
- 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 or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly, via the methods listed below. By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom/ Northern Ireland

Yellow Card Scheme

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

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.

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

Do not refrigerate or freeze. Store the immediate packaging in the outer, over wrap.

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

Before administration, the product should be inspected visually. Do not use this medicine if you notice any particulate matter and discoloration. These are visible signs of deterioration.

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.
  One ml contains 10 mg paracetamol.
  Each bag of 100 ml contains 1000 mg paracetamol
- The other ingredients are mannitol (E421), L-cysteine hydrochloride monohydrate (E920), disodium phosphate (E339), sodium hydroxide (for pH adjustment) (E524), hydrochloric acid (for pH adjustment) (E507), water for injections.

What Paracetamol looks like and contents of the pack

Solution for infusion.

Clear, colourless to slightly yellowish solution and free from visible particles.

100 ml solution contained in 100 ml polyethylene/polyamide/polypropylene (Viaflo) plastic bags, provided with one polyethylene dummy non-accessible port and one polyethylene administration port with clear/foil overpouch.

Pack sizes: pack of 40 bags.

Marketing Authorisation Holder

Marketing Authorisation Holder in Ireland and Malta:

Baxter Holding B.V.

Kobaltweg 49,

3542CE Utrecht,

Netherlands

Marketing Authorisation Holder in the UK

Baxter Healthcare Ltd

Caxton Way, Thetford,

Norfolk, IP24 3SE

United Kingdom

Manufacturer

Baxter Healthcare S.A.

Moneen Road, Castlebar, Co. Mayo, F23 XR63,

Ireland

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

Austria and Germany: Paracetamol Baxter Viaflo 10 mg/ml Infusionslösung im Beutel
Belgium and Luxemburg: Paracetamol Baxter 10 mg/ml Viaflo, solution pour perfusion
France: Paracetamol Viaflo 10 mg/ml solution pour perfusion
Greece and Cyprus: Paracetamol/Baxter 10 mg/ml Viaflo, διάλυμα για έγχυση
Denmark and Norway: Paracetamol Baxter Viaflo
Finland: Paracetamol Baxter Viaflo 10 mg/ml infuusioneste, liuos
Ireland, Malta and United Kingdom: Paracetamol 10 mg/ml Solution for Infusion
Italy: Paracetamolo Baxter Holding BV
Netherlands: Paracetamol Viaflo 10 mg/ml oplossing voor infusie
Portugal: Paracetamol Viaflo
Spain: Paracetamol RTU Baxter 10 mg/ml solución para perfusion EFG
Sweden: Paracetamol Baxter Viaflo 10 mg/ml infusionsvätska, lösning

This leaflet was last revised in April 2022

For information about this medicine or to request this leaflet in formats such as audio or large print please contact the Marketing Authorisation Holder: Tel: +44 (0)1635 206345.

----------**TEAR-OFF SECTION BELOW** ----------

The following information is intended for healthcare professionals only:

INFORMATION FOR HEALTH PROFESSIONALS

Below is a summary of the dosage, and administration details for Paracetamol. See the Summary of Product Characteristics for full prescribing information.

Intravenous use.

The medicine is restricted to adults, adolescents and children weighing more than 33 kg.

Close monitoring is needed before the end of infusion.

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.

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 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 *****
> 33 kg to ≤50kg	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

****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

The paracetamol solution is administered in intravenous infusion over 15 minutes.

Following the opening of the overpackaging, the product must be used immediately.

Before administration, the product should be visually inspected for any particulate matter and discoloration. For single use only.

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