

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. 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 Paracetamol is administered to you
3. How Paracetamol is administered to you
4. Possible side effects
5. How to store Paracetamol
6. Contents of the pack and other information

1. What Paracetamol is and what it is used for

Paracetamol contains the active substance paracetamol, an analgesic (it relieves pain) and an antipyretic (it lowers fever). This medicine is given by intravenous infusion directly into a vein. 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 restricted to term newborn infants, infants, toddlers and children weighing less than 33 kg.

2. What you need to know before Paracetamol is administered to you

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 severe liver disease

Warnings and Precautions

Talk to your doctor before you receive Paracetamol

During treatment with Paracetamol, tell your doctor straight away:

If you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

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 medicine contains paracetamol. This must be taken into account if you are using other medicines containing paracetamol or propacetamol, in order not to exceed the recommended daily dose (see section 3 “How Paracetamol is administered to you”). Inform your doctor if you are taking other medicines containing paracetamol or propacetamol.

It is very important to tell your doctor if you are taking any of the following medicines. These medicines and Paracetamol can interfere with each other:

- a medicine called probenecid (used to treat gout): a lower dose of paracetamol may be needed.
- 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.
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

Paracetamol with food, drink and 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 for advice before you are given this medicine

Pregnancy

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

Breast-feeding

Paracetamol may be used during breast-feeding.

Driving and using machines

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

Paracetamol contains sodium

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

3. How Paracetamol is administered to you

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

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

Dosage

Your doctor will determine the correct dose for you exclusively according to your body weight and individual factors.

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

50 ml vial

Patient weight	Dose per administration	Volume per administration	Maximum volume of Paracetamol, solution for infusion (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 2g

100 ml vial

Patient weight	Dose per administration	Volume per administration	Maximum volume of Paracetamol, solution for infusion (10 mg/mL) per administration based on upper weight limits of group (mL)***	Maximum Daily Dose **
> 33 kg to ≤50kg	15 mg/kg	1.5mL/kg	75 mL	60mg/kg not exceeding 3g
>50kg with additional risk factors for hepatotoxicity	1g	100mL	100mL	3g
> 50 kg and no additional risk factors for	1 g	100mL	100mL	4g

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).

****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.

In case of severe kidney failure (a situation in which the kidneys fail to function properly):

- Your doctor may adapt your dose
- Leave an interval of at least 6 hours between 2 administrations.

In case of decreased function of the liver, alcohol misuse, dehydration or malnutrition:

- The maximum daily dose must not exceed 3 g.

Method of administration

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

Intravenous use.

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

Patients weighing ≤ 10 kg:

- The glass vial/bag 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 diluted in a 0.9% sodium chloride solution or 5% glucose solution up to a maximum dilution of 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. However, this should never exceed 7.5ml per dose
- The user should refer to the product information for dosing guidelines.

For the 50 ml and 100ml vials a 0.8 mm needle (21 gauge needle) has to be used and the stopper vertically perforated at the spot specifically indicated.

For the 50ml vial:

It can also be diluted in 0.9% sodium chloride or 5% glucose up to a maximum dilution of one tenth (one volume Paracetamol into nine volumes diluent)

If you have the impression that the effect of your medicine 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
- very rare cases of 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)

The following may occur:

- a drop in blood pressure
- changes in laboratory test results:- abnormally high levels of liver enzymes found during blood checks. Regular blood checks may be required
- feeling generally unwell and run down.

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

- redness of the skin, flushing or itching
- abnormally rapid beating of the heart
- A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2)

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance Website: www.hpra.ie

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 vial and carton after EXP. The expiry date refers to the last day of that month.

Store below 30°C. Do not refrigerate or freeze. Keep the vial in the outer carton in order to protect from light.

For the 50 ml vial, after dilution in 0.9% sodium chloride or 5% glucose: do not store for more than 4 hours (infusion time included). Store below 30°C.

For single use only. This 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 discolouration. These are visible signs of deterioration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Paracetamol contains

- The active substance is paracetamol. One ml contains 10 mg paracetamol.
- Each 50 ml vial contains 500 mg paracetamol.
- Each 100 ml vial contains 1,000 mg paracetamol.
- The other ingredients are mannitol, disodium phosphate dihydrate, cysteine hydrochloride monohydrate, sodium hydroxide (4%) (for pH-adjustment), hydrochloric acid (37%) (for pH-adjustment) and water for injections.

What Paracetamol looks like and contents of the pack

Vials: 50 ml and 100 ml

Paracetamol is a solution for infusion.

It is a clear, slightly yellowish solution which is contained in a colourless glass vial with a rubber stopper and sealed with an aluminium cap.

The vials are packed in carton boxes. Each box contains:

50 ml: 10 vials.

100 ml: 1, 10 or 12 vials.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Euro House,
Euro Business Park,
Little Island,
Cork T45 K857,
Ireland

Manufacturer

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