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, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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The name of your medicine is Paracetamol 10 mg/mL Solution for infusion.
In the rest of this leaflet this medicine will be called Paracetamol.

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).
The 100 mL bottle is restricted to adults, adolescents and children weighing more than 33 kg.
The 50 mL bottle is adapted to term newborn infants, infants, toddlers and children weighing less 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 (another analgesic for infusion and a precursor of paracetamol).
- if you suffer from a severe liver disease.

Warnings and precautions
Long-term or frequent use of this medicine is not recommended. This medicine should be used only until you are able to take painkillers by mouth again.
Your doctor will ensure that you are not given higher doses than recommended as this can lead to serious liver damage.

Talk to your doctor pharmacist or nurse before using Paracetamol:
- if you suffer from a liver or kidney disease, or from alcohol abuse.
- if you are taking other medicines containing paracetamol.
- in cases of nutrition problems (malnutrition) or dehydration.
- if you suffer from Glucose 6 Phosphate Dehydrogenase (G6PD) deficiency, an enzymatic disorder of red blood cells which may lead to destruction of the red blood cells (haemolysis).
- if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking paracetamol. Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis and acute generalized exanthematous pustulosis have been reported in association with paracetamol treatment. Stop using paracetamol and seek medical attention immediately if you notice any of the symptoms described in section 4.

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

Other medicines and Paracetamol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Do not take anything else containing paracetamol while taking this medicine.

Especially tell your doctor if you are taking:
- medicines containing **paracetamol or propacetamol**; Tell your doctor if you are taking other medicines containing paracetamol or propacetamol. Your doctor will take this into account in order not to exceed the recommended daily dose (listed in section 3).
- **probenecid** (used for gout). Your doctor may reduce your Paracetamol dose in case you are taking both these medicines at the same time.
- **salicylamide** (anti-inflammatory medicine).
- medicines that **induce liver enzymes**.
- medicines used to thin your blood (**anticoagulants**), which are taken by mouth, such as warfarin. Your doctor may check-up closely the effect of the anticoagulants.
- 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.

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

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 taking this medicine.

Pregnancy
If necessary, Paracetamol can be used during pregnancy. However, in this case your doctor must evaluate if the treatment is advisable.
Ask your doctor or pharmacist for advice before taking any medicine.

Breast-feeding
Paracetamol may be used during breast-feeding.
Ask your doctor or pharmacist for advice before taking any medicine.

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

Paracetamol contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per 100 mL, that is to say essentially «sodium free».

3. How to use Paracetamol
Intravenous use.
Paracetamol will be administered to you by a healthcare professional by infusion into one of your veins.
The dose will be individually adjusted by your doctor, based on your weight and general condition.

Your doctor will ensure that you are not given higher doses than recommended.

Do not take more medicine than the label tells you to. If you do not get better, talk to your doctor.

The 100 mL bottle is restricted to adults, adolescents and children weighing more than 33 kg.
The 50 mL bottle is adapted to term newborn infants, infants, toddlers and children weighing less than 33 kg.

Dosage
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	7.5 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 hepatoxicity	1 g	100 mL	100 mL	3 g
> 50 kg and no additional risk factors for hepatoxicity	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.**
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.
***** 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 paracetamol solution is administered in intravenous infusion over 15 minutes.
If you have the impression that the effect of Paracetamol is too strong or too weak, talk to your doctor.

The following information is intended for healthcare professionals only:

Below is a summary of the dosage, dilution, administration and storage details for Paracetamol. Reference should be made to the Summary of Product Characteristics for full prescribing information.

Intravenous use.

The 100 mL bottle is restricted to adults, adolescents and children weighing more than 33 kg.
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Dosage

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> 10 kg to ≤33kg	15 mg/kg	1.5 mL/kg	49.5 mL	60 mg/kg not exceeding 2 g
> 33 kg to ≤50kg	15 mg/kg	1.5mL/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.**
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.
***** 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.

If you use more Paracetamol than you should
Talk to a doctor at once if you or your child take too much of this medicine, even if you or your child feel well. This is because too much paracetamol can cause delayed, serious liver damage.
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 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.
Possible side effects include:

Very rare (may affect up to 1 in 10,000 people):
Very rare cases of serious skin reactions have been reported.
- allergic reaction. The signs of an allergic reaction include:
- rash,
- sudden wheeziness,
- difficulty in breathing,
- swelling of the eyelids, face, lips or throat.

In isolated cases, 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.

If you experience any of the above symptoms, stop treatment immediately and inform your doctor.

Rare (may affect up to 1 in 1,000 people):
- general feeling of being unwell (malaise),
- a drop in blood pressure,
- changes in laboratory test results: abnormally high levels of hepatic enzymes found during blood checks.

Should any of the above occur, inform your doctor as regular blood checks may be required later.

Stop using paracetamol and seek medical attention immediately if you notice any of the following symptoms:
Reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome and toxic epidermal necrolysis).
A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis).

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 via Yellow Card Scheme, Website: 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.

Do not store above 30°C. Do not refrigerate or freeze.

Store the bottle in the metalised plastic pouch and in the outer carton in order to protect from light.

For the 50 mL bottle, after dilution in sodium chloride 9 mg/mL (0.9 %) solution or glucose 50 mg/mL (5 %) solution: do not store for more than 1 hour (infusion time included).

Before administration, the product should be inspected visually. Do not use this medicine if you notice any particulate matter and discoloration.

For single use only. The product should be used immediately after opening. Any unused solution should be discarded. 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. Each bottle of 100 mL contains 1 g paracetamol. Each bottle of 50 mL contains 500 mg paracetamol. 1 mL contains 10 mg paracetamol.
- The other ingredients are mannitol, disodium phosphate anhydrous, hydrochloric acid (for pH-adjustment), sodium hydroxide (for pH-adjustment) and water for injections.

What Paracetamol looks like and contents of the pack
Paracetamol 10 mg/mL solution for infusion is a clear, slightly yellowish solution for infusion. Paracetamol is packaged in carton boxes containing 50 mL polypropylene bottles. Each bottle is placed in a metalised plastic pouch. Paracetamol is packaged in carton boxes containing 100 mL polypropylene bottles. Each bottle is placed in a metalised plastic pouch. The 50 mL and 100 mL bottles are available in packs of 1, 5, 10 and 12 bottles. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder:
Noridem Enterprises Ltd., Evagorou & Makariou, Mitsi Building 3, Office 115, 1065 Nicosia, Cyprus.
Manufacturer:
DEMO S.A. PHARMACEUTICAL INDUSTRY, 21st km National Road Athens-Lamia, 14568 Krioneri, Attiki, Greece, **T:** +30 210 8161802, **F:** +30 2108161587.

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Method of administration

RISK OF MEDICATION ERRORS
Caution should be taken to avoid dosing errors due to confusion between milligram (mg) and milliliter (mL), which could result in accidental overdose and death.

The paracetamol solution is administered in intravenous infusion over 15 minutes.
Patients weighing ≤10 kg:
- The bottle 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 bottle and could be administered undiluted or diluted in a sodium chloride 9 mg/mL (0.9 %) solution or glucose 50 mg/mL (5 %) solution up to one tenth (one volume Paracetamol into nine volumes diluent) and administered over 15 minute.
- 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 be referred to the product information for dosing guidelines.
- For the 50 mL and 100 mL bottles, a 0.8 mm needle (21 gauge needle) has to be used and the stopper vertically perforated at the spot specifically indicated.
- It can also be diluted in sodium chloride 9 mg/mL (0.9 %) solution or glucose 50 mg/mL (5 %) solution up to one tenth (one volume Paracetamol into nine volumes diluent).
- The diluted solution should be visually inspected and must not be used if opalescence, visible particulate matter or precipitate are found.