Package leaflet: Information for the patient

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.

What is in this leaflet

1. What Paracetamol is and what it is used for
2. What you need to know before you use Paracetamol
3. How to use Paracetamol
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.

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 and related to paracetamol)
- if you suffer from severe liver disease.

Warnings and precautions
Talk to your doctor or pharmacist before using Paracetamol
- Do not exceed the recommended dose. Doses higher than those recommended entail the risk of very serious liver damage. Symptoms of liver damage are not usually seen until 2 days, and up to a maximum of 4-6 days, after administration.
- Take care not to exceed the maximum dose of paracetamol if you are using other medicines containing paracetamol or propacetamol (see section 2 “Other medicines and Paracetamol”)
- Dose adjustment may be necessary in the following cases:
  - liver or kidney disease
  - alcohol abuse
  - nutrition problems (malnutrition)
  - dehydration.

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

Your doctor will switch to a suitable analgesic for oral use (via the mouth) as soon as this is possible.

Children and adolescents
The size of the 100 ml vial is restricted to adolescents and children weighing more than 33 kg.

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 to use Paracetamol"). 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:
- probenecid (medicine used to treat gout): a lower dose of paracetamol may be needed
- salicylamide (medicine used to treat pain and inflammation)
- anticoagulants taken via the mouth (such as warfarin, acenocoumarol or phenprocoumon). Closer check-ups of the effect of the anticoagulant are recommended.
- barbiturates such as phenobarbital and carbamazepine (medicines used in epilepsy)
- isoniazid and rifampicin (medicines used to treat tuberculosis).

Paracetamol with alcohol
Limit the use of alcohol during treatment with this medicine.

Pregnancy and breast-feeding
Inform your doctor if you are pregnant. If necessary, Paracetamol can be used during pregnancy. However, in this case the doctor must evaluate if the treatment is advisable. You should receive the lowest possible dose that reduces your pain and/or your fever for the shortest time possible.

Paracetamol may be used during 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 this medicine is given to you.

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 sodium (23 mg) per 100 ml, that is to say essentially 'sodium free'.

3. How to use Paracetamol

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

The recommended dose is 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 ≤50 kg	15 mg/kg	1.5 ml/kg	75 ml	60 mg/kg not exceeding 3 g

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 *
>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

***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.

Method of use

RISK OF MEDICATION ERRORS
Take care to avoid dosing errors due to confusion between milligram (mg) and millilitre (ml), which could result in accidental overdose and death.

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

Intravenous use.
This medicine is given as a slow infusion (drip) into a vein over 15 minutes.
Close monitoring is needed before the end of the infusion.
For single use only.
Any unused solution should be discarded.

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
Because of the risk of delayed, serious liver damage, immediately contact your doctor even if you feel well if too much Paracetamol has been administered to you. In overdose cases, symptoms generally appear within the first 24 hours. These symptoms comprise nausea (feeling sick), vomiting, anorexia, a pale appearance to the skin and abdominal pain.

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

4. Possible side effects

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

The following may occur:

Common, may affect up to 1 in 10 people
- local reactions (such as pain and burning sensation) at the injection site.

Rare side effects, may affect up to 1 in 1,000 people
- a drop in blood pressure
- abnormally high levels of liver enzymes found during blood checks. Regular blood checks may be required.
- feeling generally unwell and run down.

Very rare side effects, may affect up to 1 in 10,000 people
- a serious skin rash or allergic reaction. **Stop the treatment immediately and inform your doctor**.
  Signs of allergic reactions may be skin redness, flushing, itching and abnormally rapid heart rate, sudden difficulty in breathing, speaking or swallowing, feeling dizzy, sick or faint, or experiencing dizziness when standing up.
- abnormally low levels of some types of blood cells (platelets, white blood cells), possibly leading to bleeding from the nose or gums. Your doctor may have to check your blood regularly.

Very rare cases of serious skin reactions have been reported.

Frequency not known (frequency cannot be estimated from the available data)
- faster heartbeat
- skin redness, flushing, itching.

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side affects 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.

Do not refrigerate or freeze.
This medicine does not require any special storage conditions.

Shelf life after first opening of the vial:
Use immediately after opening.

Before administration, the product should be inspected visually. Do not use this medicine if you notice any particulate matter or 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. Each ml contains 10 mg of paracetamol.

Each vial (100 ml) contains 1000 mg of paracetamol.

- The other ingredients are mannitol, disodium phosphate dihydrate, cysteine hydrochloride monohydrate, sodium hydroxide (for pH-adjustment), hydrochloric acid (for pH-adjustment) and water for injections.

What Paracetamol looks like and contents of the pack
This medicine is presented as a solution for infusion.
It is a clear colourless to slightly yellowish and particle-free solution which is contained in a 100-ml colourless type II glass vial with a bromobutyl rubber stopper and sealed with an aluminium flip-off cap.

The vials are packed in carton boxes. Each box contains 1 or 10 vials.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers
Marketing Authorisation Holder
Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers
SM Farmaceutici SRL., Zona industriale, 85050 TITO – POTENZA, Italy.
Neogen Developments N.V., Square Marie Curie, 50, 1070 Anderlecht, Belgium.
Salutas Pharma GmbH., Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

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

Austria:	Paracetamol Sandoz 10 mg/ml -Infusionslösung
Belgium:	Paracetamol Sandoz 10 mg/ml oplossing voor infusie
Finland:	Paracetamol Sandoz 10 mg/ml infuusioneste, liuos
Germany (RMS):	Paracetamol Hexal 10 mg/ml Infusionslösung
Ireland:	Paracetamol 10 mg/ml solution for infusion
Luxembourg:	Paracetamol Sandoz 10 mg/ml solution pour perfusion
Portugal:	Paracetamol Sandoz (10mg/ml Solução para perfusão)
United Kingdom	Paracetamol 10 mg/ml Solution for Infusion

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