

Paracetamol 10mg/ml Solution for Infusion

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, nurse or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- 1 What Paracetamol 10mg/ml Solution for Infusion is and what it is used for
- 2 What you need to know before you use Paracetamol 10mg/ml Solution for Infusion
- 3 How to use Paracetamol 10mg/ml Solution for Infusion
- 4 Possible side effects
- 5 How to store Paracetamol 10mg/ml Solution for Infusion
- 6 Contents of the pack and other information

1 What Paracetamol 10mg/ml Solution for Infusion is and what it is used for

Paracetamol 10mg/ml Solution for Infusion is an analgesic (it relieves pain) and an antipyretic (it lowers fever).

- The 100 ml vial is restricted to adults, adolescents and children weighing more than 33 kg.
- The 50 ml vial 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 10mg/ml Solution for Infusion Do not use Paracetamol 10mg/ml Solution for Infusion if you:

- are **allergic to paracetamol** or any of the other ingredients of this medicine (listed in section 6). An allergic reaction may include a rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.
- are **allergic to propacetamol** (another analgesic similar to paracetamol).
- suffer from severe **liver** disease.

Warnings and precautions

Talk to your doctor or pharmacist before using Paracetamol 10mg/ml Solution for Infusion

- Use a suitable **oral pain killer** as soon as this administration route is possible
- 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**

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

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Other medicines and Paracetamol 10mg/ml Solution for Infusion

Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines. Take particular care if you are taking the following medicines while under treatment with Paracetamol 10mg/ml Solution for Infusion:

- other paracetamol-containing products, in order not to exceed the recommended daily dose.
- probenecid.
- salicylamide.
- oral anticoagulants. More check-ups to look at the effect of the anticoagulant might be needed.

Pregnancy and breast-feeding

Inform your doctor or nurse if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby.

If necessary, Paracetamol 10mg/ml Solution for Infusion can be used during pregnancy. Your doctor should use the lowest possible dose that reduces your pain and/or your fever and use it for the shortest time possible. Contact your doctor or midwife if the pain and/or fever are not reduced or if you need to receive the medicine more often.

Ask your doctor, nurse or pharmacist for advice before taking any medicine.

Important information about some of the ingredients of Paracetamol 10mg/ml Solution for Infusion

This medicine contains less than 1 mmol sodium (23 mg) per 50ml vial and 100ml vial, that is to say essentially 'sodium-free'.

3 How to use Paracetamol 10mg/ml Solution for Infusion

For intravenous use (injection into a vein).

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

Dosage

Do not take anything else containing paracetamol while using this medicine.

The dose you will be given will be decided by the doctor and will depend on your weight, liver and kidney function.

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The following information is intended for medical or healthcare professionals only:

Paracetamol 10mg/ml Solution for Infusion

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

Dosage

Dosing based on patient weight (please see table below):

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***
≤10kg*	7.5 mg/kg	0.75 mL/kg	7.5mL	30mg/kg
> 10kg to ≤33kg	15mg/kg	1.5mL/kg	49.5mL	60mg/kg not exceeding 2g
> 33kg to ≤50kg	15 mg/kg	1.5mL/kg	75mL	60mg/kg not exceeding 3g
>50kg with additional risk factors for hepatotoxicity	1g	100mL	100mL	3g
> 50kg and no additional risk factors for hepatotoxicity	1g	100mL	100mL	4g

* Pre-term newborn infants: No safety and efficacy data are available for pre-term newborn infants.

**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.

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≤10kg*	7.5mg/kg	0.75mL/kg	7.5mL	30mg/kg
>10kg to ≤33kg	15mg/kg	1.5mL/kg	49.5mL	60mg/kg not exceeding 2g
>33kg to ≤50kg	15mg/kg	1.5mL/kg	75mL	60mg/kg not exceeding 3g
>50kg with additional risk factors for hepatotoxicity	1g	100mL	100mL	3g
>50kg and no additional risk factors for hepatotoxicity	1g	100mL	100mL	4g

* **Pre-term newborn infants:** No safety and efficacy data are available for pre-term newborn infants.

** **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.

In patients weighing 50kg or less or with risk factors, you will be given a maximum dose of 3g per day.

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

If you have the impression that the effect of Paracetamol 10mg/ml Solution for Infusion is too strong or too weak, talk to your doctor.

If you are given more Paracetamol 10mg/ml Solution for Infusion than you should

Talk to a doctor at once if you are given too much of this medicine even if you 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, nurse or pharmacist.

4 Possible side effects

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

Contact your doctor or nurse and stop treatment immediately if you experience an allergic reaction with symptoms such as swelling of the face, lips, tongue and throat, difficulty breathing or swallowing or a skin rash.

Tell your doctor or nurse if you experience the following side effects:

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

- a general feeling of being unwell (malaise)
- a drop in blood pressure
- changes in liver 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)

- other changes in laboratory test results which may result in regular blood checks: abnormally low levels of some types of blood cells (platelets, white cells) can occur, possibly leading to bleeding from the nose or gums.

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No more than 4 doses to be given in 24 hours.

*** **Maximum daily dose:** The maximum daily dose as presented in the table overleaf is for patients that are not receiving other paracetamol containing products and should be adjusted accordingly taking such products into account.

Do not exceed the stated dose.

Kidney disease:

It is recommended when giving paracetamol to patients with severe renal impairment (creatinine clearance ≤ 30mL/min), to increase the minimum interval between each administration to 6 hours.

Method of administration

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.

The paracetamol solution is administered as a 15-minute intravenous infusion (injection into a vein).

Patients weighing ≤ 10kg

- The glass vial should not be hung as an infusion due to the small volume of the medicinal product to be administered in this population

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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.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 the 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 10mg/ml Solution for Infusion

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Store below 30°C. Protect from light. Store in the original package. Do not refrigerate or freeze.

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 10mg/ml Solution for Infusion contains

- The active substance is paracetamol.
- One ml contains 10mg paracetamol.
- Each 50ml vial contains 500mg paracetamol
- Each 100ml vial contains 1000mg paracetamol in 100ml.
- The other ingredients are: cysteine hydrochloride monohydrate, disodium phosphate dihydrate, hydrochloric acid (1M) (for pH-adjustment), sodium hydroxide (1M) (for pH-adjustment), mannitol, water for injections.

What Paracetamol 10mg/ml Solution for Infusion looks like and contents of the pack

Vials 50ml and 100ml

Paracetamol 10mg/ml Solution for Infusion is a clear solution.

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

- 50ml: 10 vials
- 100ml: 10 vials

Marketing Authorisation Holder

Accord Healthcare Limited
Sage House
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North Harrow
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Manufacturer

SM Farmaceutici SRL
Zona industriale – 85050 Tito
Potenza
Italy

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Accord Healthcare Ltd, North Harrow, HA1 4HF, UK

- 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 one tenth (one volume paracetamol, solution for infusion, 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 be referred to the product information for dosing guidelines.

50ml and 100ml vials

- A 0.8mm needle (21 gauge needle) has to be used and the stopper vertically perforated at the spot specifically indicated
- 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 infusion applies particularly for central route infusions, in order to avoid air embolism
- Do not use Paracetamol 10mg/ml Solution for Infusion if you notice any particulate matter and discolouration
- For single use only. The product should be used immediately after opening. Any unused solution should be discarded.

50ml vial

- This medicine can also be diluted in 0.9% sodium chloride or 5% glucose up to one tenth (one volume paracetamol into nine volumes diluent).

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