



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

PARACETAMOL INJECTION

Paracetamol Injection BP 300mg/2ml

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again before, during or after use of this medicine.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please inform your health care provider.

In this leaflet:

1. What Paracetamol injection is and what it is used for
2. What you need to know before you are given Paracetamol injection
3. How to take Paracetamol injection
4. Possible side effects
5. How to store Paracetamol injection
6. Contents of the pack and other information

1. WHAT PARACETAMOL INJECTION IS AND WHAT IT IS USED

Paracetamol injection is an analgesic (it relieves pain) and an antipyretic (it lowers fever). 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 ARE GIVEN PARACETAMOL 300mg INJECTION

You should not be given Paracetamol Injection if you:

- are allergic to paracetamol or any of the other ingredients of this injection. 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 like paracetamol).
- suffer from severe liver disease.

Warnings and precautions

Talk to your doctor or pharmacist before using Paracetamol Injection

- 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.

Taking other medicines with Paracetamol injection

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 injection:

- other paracetamol-containing products, in order not to exceed the recommended daily



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PARACETAMOL INJECTION

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dose.

- probenecid.
- salicylamide.
- oral anticoagulants. [More check-ups to look at the effect of the anticoagulant might be needed].

Pregnancy

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

Breast-feeding

Inform your doctor or nurse if you are breastfeeding.

Driving and using machines

Some people may have sight problems or feel dizzy while taking this medicine. If this happens to you, wait until your sight returns to normal or you stop feeling dizzy before driving or using any tools or machines.

3. HOW TO TAKE PARACETAMOL INJECTION

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

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

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 ?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 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



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interval between each administration in patients with severe renal insufficiency must be at least 6 hours. No more than 4 doses are to be given in 24 hours.

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 300mg injection is too strong or too weak, talk to your doctor.

If you are given more Paracetamol injection 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, Paracetamol 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.

Not Known (frequency cannot be estimated from 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 healthcare provider. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.



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PARACETAMOL INJECTION

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5. HOW TO STORE PARACETAMOL INJECTION

- Keep all medicines out of the reach of children.
- Do not use this medicine after the expiry date 'Exp. Date' which is stated on the label and carton. 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 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. FURTHER INFORMATION

What Paracetamol Injection contains

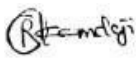


The active substance of Paracetamol Injection is Paracetamol 300mg/2ml.

What Paracetamol Injection looks like and contents of the pack

Paracetamol Injection is a clear solution packed as 10x2ml ampoule, placed in an outer carton with patient information leaflet.

MANUFACTURER

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