

## **PARACETAMOL IV INFUSION**

Paracetamol BP 1000mg/100ml

### **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 IV Infusion is and what it is used for
2. What you need to know before you are given Paracetamol IV Infusion
3. How to take Paracetamol IV Infusion
4. Possible side effects
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6. Contents of the pack and other information

### **1. WHAT PARACETAMOL IV INFUSION IS AND WHAT IT IS USED FOR**

Paracetamol IV Infusion 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 IV INFUSION**

You should not be given Paracetamol IV Infusion:

- If you are allergic to paracetamol or any of the other ingredients. An allergic reaction may include a rash, itching, difficulty breathing or swelling of the face, lips, throat, or tongue.
- If you are allergic to propacetamol (another analgesic like paracetamol).
- If you suffer from severe liver disease

### **Warnings and precautions**

Talk to your doctor or pharmacist before using Paracetamol IV Infusion

- 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 IV Infusion**

Tell your doctor 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 IV Infusion:

- Other paracetamol-containing products, in order not to exceed the recommended daily dose.
- A dose reduction should be considered for concomitant treatment with
  - Probenecid.
  - Salicylamide.
  - Oral anticoagulants. More check-ups to look at the effect of the anticoagulant might be needed.

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

### Pregnancy

Inform your doctor or pharmacist if you are pregnant, think you may be pregnant or are planning to have a baby. Paracetamol IV infusion may be used during pregnancy. However, in this case the doctor must evaluate if the treatment is advisable.

### Breast-feeding

Paracetamol IV infusion may be used during breast-feeding. Inform and ask your doctor or pharmacist if you are breast-feeding.

### 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 IV INFUSION

The dose you will be given will be decided by the doctor and will depend on your weight, liver, and kidney function. You should not be given more medicine than the label says. Do not exceed the stated dose.

### Intravenous use

Paracetamol IV Infusion 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.

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 below)

S/N	BODY WEIGHT	DOSE
1	≤10kg*	Dose per administration - 7.5mg/kg Volume per administration - 0.75mL/kg **Maximum volume of Paracetamol IV Infusion (10mg/mL) per administration based on upper weight limits of group (mL) - 7.5mL ***Maximum Daily Dose - 30mg/kg
2	> 10 kg to ≤33kg	Dose per administration - 15mg/kg Volume per administration - 1.5mL/kg **Maximum volume of Paracetamol IV Infusion (10mg/mL) per administration based on upper weight limits of group (mL) - 49.5mL ***Maximum Daily Dose - 60mg/kg not exceeding 2g
3	> 33kg to ≤50kg	Dose per administration - 15mg/kg Volume per administration - 1.5mL/kg **Maximum volume of Paracetamol IV Infusion (10mg/mL) per administration based on upper weight limits of group (mL) - 75mL ***Maximum Daily Dose - 60mg/kg not exceeding 3g
4	>50kg with additional risk factors for hepatotoxicity	Dose per administration - 1g Volume per administration - 100mL **Maximum volume of Paracetamol IV Infusion (10mg/mL) per administration based on upper weight limits of group (mL) - 100mL ***Maximum Daily Dose - 3g
5	>50kg and no additional risk factors for hepatotoxicity	Dose per administration - 1g Volume per administration - 100mL **Maximum volume of Paracetamol IV Infusion (10mg/mL) per administration based on upper weight limits of group (mL) - 100mL ***Maximum Daily Dose - 4g

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

\*\***Patients weighing less than 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 IV Infusion is too strong or too weak, talk to your doctor.

**If you or your child use more Paracetamol IV Infusion than you or your child should use, talk to a doctor at once. This is because too much paracetamol can cause delayed, serious liver damage.**

In overdose cases, symptoms generally appear within the first 24 hours and comprises of nausea, vomiting, anorexia, pallor, abdominal pain, and a risk of liver injury.

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

#### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Paracetamol IV Infusion can cause side effects although not everybody gets them. Contact your doctor or pharmacist 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 pharmacist 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 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

#### **Reporting of side effects**

If you get any side effects, talk to your doctor, or healthcare provider. This includes any possible side effects not listed in this leaflet.

#### **5. HOW TO STORE PARACETAMOL IV INFUSION**

- Keep all medicines out of reach of children.
- Do not use this medicine after the expiry date which is stated as "Exp. Date" 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 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. FURTHER INFORMATION

### What Paracetamol IV Infusion contains




Paracetamol IV Infusion contains the active substance Paracetamol.

### What Paracetamol IV Infusion looks like and contents of the pack

Paracetamol IV Infusion is a clear solution packed as 50ml and 100ml in a LDPE, placed in a carton with insert.

## SUPPLIER AND MANUFACTURER

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