Paracetamol 10mg/ml Solution for Infusion

Read all of this leaflet carefully before you are given this medicine:
• 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. 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 gets worse, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:
1 What Paracetamol 10mg/ml Solution for Infusion is and what it is used for
2 Before you use
3 How to use
4 Possible side effects
5 How to store
6 Further information

1 What Paracetamol 10mg/ml Solution for Infusion is and what it is used for
Paracetamol 10mg/ml Solution for Infusion is used as an analgesic (relieves pain) and an antipyretic (lowers fever). It is used for:
• short-term treatment of moderate pain, especially following surgery
• short-term treatment of fever

2 Before you use
Do not use Paracetamol 10mg/ml Solution for Infusion if you:
• are allergic (hypersensitive) to paracetamol or any of the other ingredients of Paracetamol 10mg/ml Solution for Infusion. An allergy may range from a skin rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.
• are allergic (hypersensitive) to propacetamol or any other analgesic similar to paracetamol.
• suffer from severe liver disease

Take special care with Paracetamol 10mg/ml Solution for Infusion:
• Use a suitable oral pain killer as soon as possible.
• If you suffer from a liver disease, severe kidney disease or from alcohol abuse.
• If you are taking other medicines containing paracetamol.
• In case of nutrition problems (malnutrition) or dehydration. Inform your doctor/treatment of any of the above mentioned conditions apply to you.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription and medicinal products.
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.
• anticoagulants.
• Check up to look at the effect of the anticoagulant might be needed.

3 How to use
For enzymatic use (injection into a vein). The 50ml vial is restricted to term newborn infants, infants, toddlers and children weighing less than 15kg.
The 100ml vial is restricted to adults, adolescents and children weighing more than 15kg.

4 Possible side effects
• Swelling of the face, lips, throat or tongue.
• Allergic (hypersensitive) to paracetamol or any of the other ingredients of Paracetamol 10mg/ml Solution for Infusion. An allergic reaction may range from a skin rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.

5 How to store

6 Further information

Paracetamol 10mg/ml Solution for Infusion

Take particular care with Paracetamol 10mg/ml Solution for Infusion:
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Dosage
Dosing based on patient weight (please see table below):

Patient weight
≤15kg*  >15kg to <33kg  >33kg to ≤50kg  >50kg

Dosage per administration
7.5mg/kg  5mg/kg  3mg/kg  2mg/kg

Volume per administration
0.75mL/kg  1.5mL/kg  2.5mL/kg  4mL/kg

Maximum volume of paracetamol, solution for infusion (10mg/ml) per administration:
Based on upper weight limits of group (mL)****

≤15kg*  >15kg to <33kg  >33kg to ≤50kg  >50kg

Maximum Daily Dose **
75mg/kg  50mg/kg  30mg/kg  20mg/kg

Paracetamol IV 10mg/ml Solution for Infusion PIL - UK

Paracetamol 10mg/ml Solution for Infusion

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**Paracetamol IV 10mg/ml Solution for Infusion PIL - UK**

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

**Maximum daily dose:** The maximum daily dose as presented in the table below 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.

No more than 4 doses to be given in 24 hours. With severe renal insufficiency must be at least 6 hours.

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***Patients weighing less will require smaller volumes.***

### Possible side effects

Like all medicines, Paracetamol 10mg/ml Solution for Infusion can cause side effects, although not everybody gets them.

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

- **Gastrointestinal:** feeling or being sick, weight loss, or fever is likely to return. Do not take a double dose to make up for a forgotten dose. If you forget to use Paracetamol 10mg/ml Solution for Infusion, talk to your doctor or pharmacist.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme of the MHRA website provided below:

**How to store**

Keep out of the sight and reach of children. Do not use Paracetamol 10mg/ml Solution for Infusion after the expiry date which is stated on the label and other cartons. 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.

### Further information

**What Paracetamol 10mg/ml Solution for Infusion contains**

- The active substance is paracetamol.

- One milligram contains 10 milligrams of paracetamol.

- Each 50ml vial contains 500 milligrams of paracetamol.

- Each 100ml vial contains 1000 milligrams of paracetamol.

- The other ingredients are: sodium hydroxide monohydrate, disodium phosphate dihydrate, hydrochloric acid (1M), sodium hydroxide (1M for pH adjustment), sodium chloride (0.9% for administration), water for injection.

**What Paracetamol 10mg/ml Solution for Infusion looks like and contains of this 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, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom.

**Manufacturer**

SM Farmaceutici SRL, Zona industriale – 85050 Tito, Potenza, Italy

The leaflet was last reviewed in August 2017

**If you would like a leaflet with larger text, please contact 01271 385257**

**Method of administration**

**Risk of medication errors**

Take care to avoid dosing errors due to confusion between milligrams (mg) and millilitres (mL), which could result in accidental overdose and death.

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

As for all solutions for infusion presented in glass, it should be remembered that dosing monitoring is needed especially 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 particular matter and discoloration.

For single use only. The product should be used immediately after opening. Any unused solution should be disposed of immediately.

For the 50ml and 100ml vials, a 0.8mm needle (21 gauge needle) has to be used and the stopper venturized at the spot specifically indicated.

For the 50ml vial, it can also be diluted in 9% sodium chloride or 5% glucose up to one tenth (one volume paracetamol into nine volumes diluent).

**Paracetamol IV 10mg/ml Solution for Infusion PIL - UK**

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**Colours**

1. Black

2. Red

3. Green

4. Blue

5. Yellow

6. Orange

**Non Printing Colours**