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 serious, 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. How to use
3. Possible side effects
4. How to store
5. Further information

What Paracetamol 10mg/ml Solution for Infusion is and what it is used for
Paracetamol 10mg/ml Solution for Infusion is an analgesic and an antipyretic (lowers fever).
It is used for:
- short-term treatment of fever.
- mild pain such as from headache, backache or menstruation.
- for pain that does not require an opioid analgesic.
- to replace a paracetamol-containing product that you have run out of, in order not to exceed the recommended daily dose.

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.
- have had a reaction to this medicine in the past.
- are suffering from severe liver disease.

How to use
For intravenous use (injection into a vein).
The dose you will be given will be decided by the doctor and will take your weight into consideration.

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

<table>
<thead>
<tr>
<th>Patient weight</th>
<th>Dose per administration</th>
<th>Volume per administration</th>
<th>Maximum volume of paracetamol, solution for infusion/100ml per administration based on upper weight limits of group (mL)***</th>
<th>Maximum Daily Dose **</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤50kg</td>
<td>15mg/kg</td>
<td>0.75mL/kg</td>
<td>7.5mL</td>
<td>30mg/kg</td>
</tr>
<tr>
<td>&gt;50kg to ≤100kg</td>
<td>15mg/kg</td>
<td>1.5mL/kg</td>
<td>45mL</td>
<td>60mg/kg (not exceeding 2g)</td>
</tr>
<tr>
<td>&gt;100kg to ≤150kg</td>
<td>15mg/kg</td>
<td>1.5mL/kg</td>
<td>75mL</td>
<td>60mg/kg (not exceeding 2g)</td>
</tr>
<tr>
<td>&gt;150kg with additional risk factors for hepatotoxicity</td>
<td>1g</td>
<td>100mL</td>
<td>100mL</td>
<td>3g</td>
</tr>
<tr>
<td>&gt;33kg and no additional risk factors for hepatotoxicity</td>
<td>1g</td>
<td>100mL</td>
<td>100mL</td>
<td>4g</td>
</tr>
</tbody>
</table>

Take special care with Paracetamol 10mg/ml Solution for Infusion
- Use a suitable oral pain killer as soon as possible.
- If you suffer from liver disease, severe kidney disease or from alcohol abuse.

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 or herbal medicines and natural products.
Talk 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.
- use anticoagulants. More check-ups to look at the effect of the anticoagulant might be needed.

Paracetamol 10mg/ml Solution for Infusion
The medicinal product contains 4.32 mmol sodium per dose. To be taken into consideration by patients on a controlled sodium diet.

Important information about some of the ingredients of Paracetamol 10mg/ml Solution for Infusion
This medicinal product contains propacetamol (another analgesic similar to paracetamol).

Additional risk factors
- obesity
- age > 65 years
- kidney disease
- liver disease
- alcohol abuse
- conditions affecting the metabolism of paracetamol (e.g. malnutrition) or from other medicines
- medicines lowering the blood pressure
- during or after high/long physical or mental stress
- concurrent anticoagulant therapy

Possible side effects
An allergic reaction may include a rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.

Special precautions for use
Take particular care with Paracetamol 10mg/ml Solution for Infusion
- if you have any of the above mentioned conditions apply to you.

Further information
The following information is intended for medical or healthcare professionals only.
Paracetamol 10mg/ml Solution for Infusion
The 50ml vial is restricted 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
Dosage based on patient weight (please see table below):

<table>
<thead>
<tr>
<th>Patient weight</th>
<th>Dose per administration</th>
<th>Volume per administration</th>
<th>Maximum volume of paracetamol, solution for infusion/100ml per administration based on upper weight limits of group (mL)***</th>
<th>Maximum Daily Dose **</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤50kg</td>
<td>15mg/kg</td>
<td>0.75mL/kg</td>
<td>7.5mL</td>
<td>30mg/kg</td>
</tr>
<tr>
<td>&gt;50kg to ≤100kg</td>
<td>15mg/kg</td>
<td>1.5mL/kg</td>
<td>45mL</td>
<td>60mg/kg (not exceeding 2g)</td>
</tr>
<tr>
<td>&gt;100kg to ≤150kg</td>
<td>15mg/kg</td>
<td>1.5mL/kg</td>
<td>75mL</td>
<td>60mg/kg (not exceeding 2g)</td>
</tr>
<tr>
<td>&gt;150kg with additional risk factors for hepatotoxicity</td>
<td>1g</td>
<td>100mL</td>
<td>100mL</td>
<td>3g</td>
</tr>
<tr>
<td>&gt;33kg and no additional risk factors for hepatotoxicity</td>
<td>1g</td>
<td>100mL</td>
<td>100mL</td>
<td>4g</td>
</tr>
</tbody>
</table>

Important information about some of the ingredients of Paracetamol 10mg/ml Solution for Infusion
This medicinal product contains 4.32 mmol sodium per dose. To be taken into consideration by patients on a controlled sodium diet.

Further information
The following information is intended for medical or healthcare professionals only.
Paracetamol 10mg/ml Solution for Infusion
The 50ml vial is restricted 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
Dosage based on patient weight (please see table below):

<table>
<thead>
<tr>
<th>Patient weight</th>
<th>Dose per administration</th>
<th>Volume per administration</th>
<th>Maximum volume of paracetamol, solution for infusion/100ml per administration based on upper weight limits of group (mL)***</th>
<th>Maximum Daily Dose **</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤50kg</td>
<td>15mg/kg</td>
<td>0.75mL/kg</td>
<td>7.5mL</td>
<td>30mg/kg</td>
</tr>
<tr>
<td>&gt;50kg to ≤100kg</td>
<td>15mg/kg</td>
<td>1.5mL/kg</td>
<td>45mL</td>
<td>60mg/kg (not exceeding 2g)</td>
</tr>
<tr>
<td>&gt;100kg to ≤150kg</td>
<td>15mg/kg</td>
<td>1.5mL/kg</td>
<td>75mL</td>
<td>60mg/kg (not exceeding 2g)</td>
</tr>
<tr>
<td>&gt;150kg with additional risk factors for hepatotoxicity</td>
<td>1g</td>
<td>100mL</td>
<td>100mL</td>
<td>3g</td>
</tr>
<tr>
<td>&gt;33kg and no additional risk factors for hepatotoxicity</td>
<td>1g</td>
<td>100mL</td>
<td>100mL</td>
<td>4g</td>
</tr>
</tbody>
</table>
**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 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.

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

If you forget to use Paracetamol 10mg/ml Solution for Infusion, ask your doctor, nurse or pharmacist.

**Possible side effects**

- As a renal disease, Paracetamol 10mg/ml Solution for Infusion can cause side effects, although not everybody gets them.

Contact your doctor or nurse and stop treatment immediately if you experience the following side effects:

- The other ingredients are: sodium hydroxide (1M) (for pH-adjustment), mannitol, disodium phosphate dihydrate, hydrochloric acid (1M) (for pH-adjustment), sodium hydroxide (1M) (for pH adjustment), mannitol, water for injections.

**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). As for all solutions for infusion presented in glass vial, 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 an 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. For the 5ml and 10ml vials, a 0.8mm needle (21 gauge needle) has to be used and the stopper vertically parted at the spot specifically indicated.

For the 50ml and 100ml vials, it can be diluted with 0% sodium chloride or 5% glucose up to one tenth (one volume paracetamol into nine volumes diluent).

**Further information**

What Paracetamol 10mg/ml Solution for Infusion contains:

- The active substance is paracetamol.

- Other ingredients are: sodium hydroxide (1M) (for pH-adjustment), mannitol, 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:

- Pack size: 5ml and 10ml.

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

- The vials are packed in carton boxes. Each box contains: 5ml - 10 vials, 100ml - 10 vials.

**Marketing Authorisation Holder**

Accord Healthcare Limited, Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom.

**Manufacturer**

SM Farmaceutici SRL, Zona industrial – 85050 Tito, Potenza, Italy.

This leaflet was last revised in February 2019.

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