Below is a summary of the dosage, dilution, administration and storage details for Perfalgan 10 mg/ml, solution for infusion.

1. WHAT PERFALGAN 10 mg/ml, solution for infusion IS AND WHAT IT IS USED FOR
This medicine is an analgesic (it relieves pain) and an antipyretic (it lowers fever).
The 50 ml vial is adapted to term newborn infants, infants, toddlers and children weighing less than 33 kg.

2. BEFORE YOU USE PERFALGAN 10 mg/ml, solution for infusion
Do not use PERFALGAN 10 mg/ml, solution for infusion
- if you are allergic (hypersensitive) to paracetamol or to any of the other ingredients of Perfalgan.
- if you are pregnant.
- if you are breast-feeding.
- if you have any further questions, ask your doctor or pharmacist.

3. HOW TO USE PERFALGAN 10 mg/ml, solution for infusion
You should be referred to the product information for dosing guidelines.
- The user should be referred to the product information for dosing guidelines.
- The glass vial of Perfalgan should not be hung as an infusion due to the small volume of the medicinal product to be administered in this context.

4. POSSIBLE SIDE EFFECTS
Pre-term newborn infants:
- the paracetamol solution is administered in intravenous infusion over 15 minutes.
- The paracetamol solution is administered in intravenous infusion over 15 minutes.

5. HOW TO STORE PERFALGAN 10 mg/ml, solution for infusion
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor 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.

6. FURTHER INFORMATION
- ≥ 33 kg to ≤ 50 kg
- Administration of 7.5 mg/kg 0.75 mL/kg 7.5 mL 30 mg/kg
- Maximum volume of Perfalgan 10 mg/ml per administration based on upper weight limits of group (mL)**
- Maximum Daily Dose ***

Patient weight

<table>
<thead>
<tr>
<th>Weight Group</th>
<th>Dose per administration</th>
<th>Volume per administration</th>
<th>Maximum volume of Perfalgan 10 mg/ml per administration based on upper weight limits of group (mL)***</th>
<th>Maximum Daily Dose ***</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 10 kg</td>
<td>7.5 mg/kg</td>
<td>0.75 mL/kg</td>
<td>7.5 mL</td>
<td>30 mg/kg</td>
</tr>
<tr>
<td>&gt; 10 kg to ≤ 33 kg</td>
<td>15 mg/kg</td>
<td>1.5 mL/kg</td>
<td>15 mL</td>
<td>60 mg/kg not exceeding 3g</td>
</tr>
<tr>
<td>&gt; 33 kg to ≤ 50 kg</td>
<td>15 mg/kg</td>
<td>1.5 mL/kg</td>
<td>15 mL</td>
<td>60 mg/kg not exceeding 3g</td>
</tr>
<tr>
<td>&gt; 50 kg with additional risk factors for hepatotoxicity</td>
<td>1g</td>
<td>100 mL</td>
<td>100 mL</td>
<td>3g</td>
</tr>
<tr>
<td>&gt; 50 kg and no additional risk factors for hepatotoxicity</td>
<td>1g</td>
<td>100 mL</td>
<td>100 mL</td>
<td>4g</td>
</tr>
</tbody>
</table>

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

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

For the 50ml and 100ml vial, close monitoring is needed before the end of infusion.

Intravenous use.

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

Intravenous use.

You should not be given more medicine than the label says. Do not exceed the stated dose.

Intravenous use.

In cases of nutrition problems (malnutrition) or dehydration.

In cases of nutrition problems (malnutrition) or dehydration.

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

Taking or using other medicines.

Do not give anything else containing paracetamol while giving this medicine. This medicine contains paracetamol and this must be taken into account if other medicines containing paracetamol or propacetamol are taken, in order not to exceed the recommended daily dose (see following section).

Inform your doctor if you are taking other medicines containing paracetamol or propacetamol.

A dose reduction should be considered for concomitant treatment with Probenecid.

Please inform your doctor or pharmacist if you are taking oral anticoagulants. Closer check-ups of the effect of the anticoagulant might be necessary.

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

Breast-feeding.

Pregnancy.

Inform your doctor if you are pregnant. PERFALGAN may be used during pregnancy. However, in this case the doctor must evaluate if the treatment is advisable.

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

Reporting of side effects

If you have any further questions on the use of this product ask your doctor or pharmacist.
The paracetamol solution is administered in intravenous infusion over 15 minutes. If you have the impression that the effect of PERFALGAN 10 mg/ml solution for infusion is too strong or too weak, talk to your doctor. If you or your child use more PERFALGAN 10mg/ml, solution for infusion than if you or your child should use, talk to a doctor at once if you or your child take too much of this medicine even if you or your child seem 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 product ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, PERFALGAN 10 mg/ml solution for infusion can cause side effects, although not everybody gets them.

- In very rare cases (less than 1 in 10,000 persons, including isolated reports), a serious skin rash or allergic reaction may occur. Stop the treatment immediately and inform your doctor.
- In rare cases (more than 1 out of 1,000 persons), the following may occur: a malaise, a drop in blood pressure or changes in laboratory test results: abnormally high levels of hepatic enzymes found during blood checks. Should this occur, inform your doctor as regular blood tests should be carried out to assess the status of liver function.
- In isolated cases, other changes in laboratory test results have been observed which have necessitated regular blood checks: abnormally low levels of some types of blood cells (platelets, white cells), possibly leading to bleeding from the nose or gums. Should this occur, inform your doctor.
- 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. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE PERFALGAN 10 mg/ml, solution for infusion

Keep out of the reach and sight of children.

Do not use PERFALGAN 10 mg/ml, solution for infusion after the expiry date which is stated on the packaging after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C. Do not refrigerate or freeze.

For the 50 ml vial, after dilution in 0.9% sodium chloride or 5% glucose: do not store for more than 1 hour (infusion time included).

Before administration, the product should be inspected visually. Do not use PERFALGAN if you notice any particulate matter and discoloration.

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

6. FURTHER INFORMATION

What PERFALGAN 10 mg/ml, solution for infusion looks like and contents of the pack

Vials of 50 ml and 100 ml.

PERFALGAN 10 mg/ml solution for infusion is a clear and slightly yellowish solution.

PERFALGAN 10 mg/ml solution for infusion vials are supplied in packs of 12 vials.

Not all pack sizes or presentation may be marketed.

Marketing Authorisation Holder

Bristol-Myers Squibb Pharmaceuticals Ltd

BMS House

Uxbridge Business Park

Sanderson Road

Uxbridge

Middlesex UB8 10H

United Kingdom

Manufacturer

BRISTOL MYERS SQUIBB

Loc. Fontana del Ceraso

Anagni, Italy

or

BIEFFE MEDITAL S.p.A.

Via Nueva Promontorio, nc

23034 GROSUTTO-SO, Italy

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria: PERFALGAN

Czech Republic: PERFALGAN

Estonia: PERFALGAN

Finland: PERFALGAN

France: PERFALGAN

Germany: PERFALGAN

Hungary: PERFALGAN

Iceland: PERFALGAN

Ireland: PERFALGAN

Italy: PERFALGAN

Lithuania: PERFALGAN 10 mg/ml

Portugal: PERFALGAN 10 mg/ml

Spain: PERFALGAN 10 mg/ml

U.K.: PERFALGAN 10 mg/ml

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder:

This leaflet was last revised in January 2016.

**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.

Method of administration

**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 in intravenous infusion over 15 minutes. Patients weighing 4.5 kg:

- The glas vial of Perfalgan should not be hung as an infusion due to the small volume of the medicinal product to be administered in this population.
- 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 Perfalgan into nine volumes diluent) and administered over 15 minutes.
- A 4.5 or 10 ml syringe should be used to measure the dose 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. For the 50ml and 100ml vials, a 0.8 mm needle (21 gauge needle) has to be used and the stopper vertically perforated at the spot specifically indicated.
- It can also be diluted in 0.9% sodium chloride or 5% glucose up to one tenth (one volume Perfalgan into nine volumes diluent). The diluted solution should be visually inspected and must not be used if opalescence, visible particulate matter or precipitate are found.