

Perfalgan

10 mg/mL Solution for Infusion

Paracetamol
Read all of this leaflet carefully before you start using this medicine.

- 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 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 gets serious, or if you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

What is in this leaflet

1. What PERFALGAN 10 mg/mL Solution for Infusion is and what it is used for
2. Before you use PERFALGAN 10 mg/mL Solution for Infusion
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4. Possible side effects
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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 100 mL vial or 100 mL bag is restricted to adults, adolescents and children weighing more than 33 kg. The 50 mL vial is restricted to term newborn infants, infants, toddlers and children weighing less than 33 kg. It is indicated for the short-term treatment of moderate pain, especially following surgery, and for the short-term treatment of fever.

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 allergic (hypersensitive) to propacetamol (another analgesic for infusion and a precursor of paracetamol)
- If you suffer from severe liver disease.

Take special care with PERFALGAN 10 mg/mL Solution for Infusion

- Use a suitable analgesic oral treatment as soon as this administration route is possible
- If you suffer from 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 applies to you.

Taking PERFALGAN 10 mg/mL Solution for Infusion with other medicines

This medicine contains paracetamol and this must be taken into account if other medicines containing paracetamol or propacetamol are used, 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 reduction of the paracetamol dose should be considered for concomitant treatment with probenecid.

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

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 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.

Breast-feeding

PERFALGAN may be used during breast-feeding.

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

Important information about some of the other ingredients of PERFALGAN 10 mg/mL Solution for Infusion

This medicine contains less than 1 millimole of sodium (23 mg) per 100 mL of PERFALGAN, that is essentially "sodium free".

3. HOW TO USE PERFALGAN 10 mg/mL Solution for Infusion

Intravenous use.

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

The 50 mL vial is restricted to term newborn infants, infants, toddlers and children weighing less than 33 kg.

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

Posology

Dosing is based on patient weight (see the dosing table below).

Patient Weight	Dose per Administration	Volume per Administration	Maximum Volume of PERFALGAN (10 mg/mL) per Administration based on Upper Weight Limits of Group (mL)***	Maximum Daily Dose**
≤10 kg*	7.5 mg/kg	0.75 mL/kg	7.5 mL	30 mg/kg
>10 kg to ≤33 kg	15 mg/kg	1.5 mL/kg	49.5 mL	60 mg/kg not exceeding 2 g
>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

* **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.

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.

Patients weighing ≤10 kg:

- The glass vial/bag of PERFALGAN should not be hung as an infusion due to the small volume of the medicine to be administered in this population.
- The volume to be administered should be withdrawn from the vial/bag and diluted in a 0.9% sodium chloride solution or in a 5% glucose solution up to one tenth (one volume PERFALGAN into nine volumes diluent) and administered over 15 minutes.
- A 5 or 10 mL syringe should be used to measure the dose as appropriate for the weight of the child and the desired volume. However, this should never exceed 7.5 mL per dose.
- The user should be referred to the product information for dosing guidelines.

For the 50 mL and 100 mL vials, use a 0.8 mm needle (21 gauge) and vertically perforate the stopper at the spot specifically indicated.

It can also be diluted in a 0.9% sodium chloride or 5% glucose solution up to one-tenth dilution (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.

If you have the impression that the effect of PERFALGAN 10 mg/mL Solution for Infusion is too strong or too weak, ask your doctor.

If you use more PERFALGAN 10 mg/mL Solution for Infusion than you should, contact your doctor or pharmacist immediately.

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

If you have any further questions on the use of this medicine, 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 rare cases (more than 1 out of 10,000 patients and less than 1 out of 1,000 patients), the following may occur: malaise, a drop in blood pressure or changes in laboratory test results - abnormally high levels of hepatic enzymes found in blood checks -. Should this occur, inform your doctor as regular blood checks may be required later.
 - In very rare cases (less than 1 out of 10,000 patients, including isolated reports), a serious skin rash or allergic reaction may occur. Stop the treatment immediately and inform your doctor.
 - 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 the injection site have been reported.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, inform your doctor or pharmacist.

5. HOW TO STORE PERFALGAN 10 mg/mL SOLUTION FOR INFUSION

Keep out of the sight and reach of children.

Do not use PERFALGAN 10 mg/mL Solution for Infusion after the expiry date which is stated on the pack after "EXP".

The expiry date refers to the last day of that month.

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

Keep the 100 mL bag in the outer aluminium overpackaging.

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 use, the medicine should be inspected visually. Do not use PERFALGAN if you notice any particulate matter or discoloration.

100 mL Bag: Note that there may be moisture between the bag and the outer container due to the sterilisation process. It does not impact the quality of the product.

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

6. FURTHER INFORMATION
What PERFALGAN 10 mg/mL Solution for Infusion contains

- The active substance is paracetamol. 1 mL contains 10 mg of paracetamol.
- The other ingredients are: cysteine hydrochloride monohydrate, disodium phosphate dihydrate, hydrochloric acid, mannitol, sodium hydroxide, water for injections.

What PERFALGAN 10 mg/mL Solution for Infusion looks like and contents of the pack

50 mL and 100 mL Vials

100 mL Bags

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.

PERFALGAN 10 mg/mL Solution for Infusion bags are supplied in packs of 50 bags.

Not all pack sizes or presentations may be marketed.

Marketing Authorisation Holder

BRISTOL-MYERS SQUIBB S.r.l., Via Virgilio Maroso, 50 - Rome (Italy).

Manufacturer responsible for batch release

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or

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THIS IS A MEDICAMENT

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep Medicament out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists