PACKAGE LEAFLET: INFORMATION FOR THE USER

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. 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 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 is restricted to adults, adolescents and children weighing more than 33 kg.
The 50 ml vial is adapted 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 a 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 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 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.

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 ingredients of PERFALGAN 10 mg/ml, solution for infusion

This medicinal product contains less than 1 mmol sodium (23mg) per 100 ml of Perfalgan, i.e. essentially "sodium free".

3. HOW TO USE PERFALGAN 10 mg/ml, solution for infusion

You should not be given more medicine than the label says. Do not exceed the stated dose.
Intravenous use.
Perfalgan 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 vial is restricted to adults, adolescents and children weighing more than 33 kg.
The 50 ml vial 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 table here 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	7.5mL	30 mg/kg
> 10 kg to ≤33kg	15 mg/kg	1.5mL/kg	49.5mL	60mg/kg not exceeding 2g
> 33 kg to ≤50kg	15 mg/kg	1.5mL/kg	75 mL	60mg/kg not exceeding 3g
>50kg with additional risk factors for hepatotoxicity	1g	100mL	100mL	3g
> 50 kg and no additional risk factors for hepatotoxicity	1 g	100mL	100mL	4g

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

INFORMATION FOR HEALTH PROFESSIONALS

Below is a summary of the dosage, dilution, administration and storage details for Perfalgan 10 mg/ml, solution for infusion. Reference should be made to the Summary of Product Characteristics for full prescribing information.
Intravenous use.
The 100ml vial is restricted to adults, adolescents and children weighing more than 33 kg.
The 50ml vial is adapted to term newborn infants, infants, toddlers and children weighing less than 33 kg.
For the 50ml and 100ml vial, close monitoring is needed before the end of infusion.

Dosage

Dosing based on patient weight (please see the dosing table here 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	7.5mL	30 mg/kg
> 10 kg to ≤33kg	15 mg/kg	1.5mL/kg	49.5mL	60mg/kg not exceeding 2g
> 33 kg to ≤50kg	15 mg/kg	1.5mL/kg	75 mL	60mg/kg not exceeding 3g
>50kg with additional risk factors for hepatotoxicity	1g	100mL	100mL	3g
> 50 kg and no additional risk factors for hepatotoxicity	1 g	100mL	100mL	4g

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

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 out of 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 10,000 persons and less 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 checks may be required later.
- 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.
United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

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 50ml 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 contains
- The active substance is paracetamol. One ml contains 10 mg paracetamol.
- The other ingredients are mannitol, cysteine hydrochloride monohydrate, disodium phosphate dihydrate, sodium hydroxide, hydrochloric acid, water for injections.

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 1DH
United Kingdom
Manufacturer
BRISTOL MYERS SQUIBB
Loc. Fontana del Ceraso
Anagni, Italy
or
BIEFFE MEDITAL S.p.A.
Via Nuova Provinciale, nc
23034 GROSOTTO-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

RISK OF MEDICATION ERRORS
Take care to avoid dosing errors due to confusion between milligram (mg) and milliliter (mL), which could result in accidental overdose and death.

The paracetamol solution is administered in intravenous infusion over 15 minutes.
Patients weighing ≤ 10 kg:
- 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 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 minute.
- 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 7.5ml 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.