

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
2. Before you use PERFALGAN 10 mg/ml, solution for infusion
3. How to use PERFALGAN 10 mg/ml, solution for infusion
4. Possible side effects
5. How to store PERFALGAN 10 mg/ml, solution for infusion
6. Further information

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 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 as your doctor may need to change your dose.

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.

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.

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.

** 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.

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.

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.

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.

** Maximum daily dose: The maximum daily dose as presented in the table above is for patients that are not receiving other paracetamol



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