

PACKAGE LEAFLET: INFORMATION FOR THE USER

PARACETAMOL 10 mg/ml SOLUTION FOR INFUSION

Paracetamol

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- 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 signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Paracetamol 10 mg/ml Solution for Infusion is and what it is used for
2. What you need to know before you use Paracetamol 10 mg/ml Solution for Infusion
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1. WHAT PARACETAMOL 10 mg/ml Solution for Infusion IS AND WHAT IT IS USED FOR

Paracetamol is an analgesic agent (it relieves pain) and an antipyretic agent (it reduces body temperature).

The 100-ml bag is for use in adults, adolescents and children weighing more than 33 kg (approximately 11 years of age) only.

The 50-ml bag is for use in full-term newborns, infants and children weighing less than 33 kg. The 10 ml bag is adapted for use in full-term newborns, infants and children weighing less than 10 kg.

It is indicated in the short-term treatment of moderate pain, particularly post-surgery pain, and in the short-term treatment of fever.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE PARACETAMOL 10 mg/ml Solution for Infusion

Do not use Paracetamol 10 mg/ml Solution for Infusion:

- if you are allergic (hypersensitive) to paracetamol or to any of the other ingredients.
- if you are allergic (hypersensitive) to propacetamol (another analgesic agent used for infusions, a precursor of paracetamol).
- if you suffer from serious liver disease.

Warnings and precautions

- you should use appropriate analgesic therapy administered orally as soon as this route of administration can be used,
- if you have liver or kidney disease, or in the event of alcohol abuse,
- if you are taking other paracetamol-containing medicines, □ if you have nutritional problems (malnutrition) or are dehydrated, □ if you are weighing less than 50 kg.
- Before starting treatment, tell your doctor if any of the above situations applies to you.

Other medicines and Paracetamol 10 mg/ml Solution for Infusion:

This medicine contains paracetamol: this should be taken into account if you are taking other paracetamol-based medicines, so that you do not exceed the recommended daily dose (see section below). Tell your doctor if you are taking any other paracetamol-containing medicines.

A dose reduction should be considered for concomitant treatment with probenecid

Please inform your doctor or pharmacist if you are taking oral anticoagulants. More check-ups to look at the effect of the anticoagulant might be needed.

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines.

Pregnancy, breast-feeding and fertility

Tell your doctor if you are pregnant. If necessary, Paracetamol can be used if you are pregnant, but the doctor should then assess whether this treatment is appropriate.

Paracetamol may be used while breast-feeding.

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

Paracetamol 10 mg/ml Solution for Infusion contains sodium

This medicine contains 252 mg of sodium (main component of cooking / table salt) per 100ml bag, which is equivalent to 13% of the WHO recommended maximum daily food intake of 2 g of sodium per adult.

The maximum daily dose of this product (corresponding for example to 4 bags of 100 ml) in an individual weighing more than 50 kg without additional risk factors for hepatotoxicity is equivalent to 50% of the maximum daily dose recommended by the WHO for sodium.

PARACETAMOL 10 mg / ml, solution for infusion is considered to be rich in sodium. This should be especially taken into account for those on a low salt diet.

Talk to your doctor or pharmacist if you need PARACETAMOL 10 mg / ml, solution for infusion daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

3. HOW TO USE PARACETAMOL 10 mg/ml Solution for Infusion

Paracetamol solution will be administered to you by a healthcare professional.

Dosage

The dose will depend on your weight and your general condition. Your doctor will calculate your body weight and will determine the dose you should receive.

Please see the dosing table here below :

Patient weight	Dose per administration	Volume per administration	Maximum volume of Paracetamol (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	1g	100 ml	100 ml	3 g
> 50 kg and no additional risk factors for hepatotoxicity	1g	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.

Intravenous use.

Paracetamol solution will be given by infusion into one of your veins. The infusion will last approximately 15 minutes.

It can be diluted in 0.9 % sodium chloride or 5 % glucose up to one tenth (one volume Paracetamol 10 mg/ml Solution for Infusion into nine volumes diluent).

If you have the impression that the effect of Paracetamol 10 mg/ml is too strong or too weak, talk to your doctor.

In case of an overdose, symptoms generally appear within the first 24 hours and comprise of nausea, vomiting, anorexia, pallor, abdominal pain and liver damage may occur. Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage. Please inform your doctor if you notice any of these symptoms.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

- In rare cases (more than 1 in 10,000 people but fewer than 1 in 1,000 people), malaise, a drop in blood pressure or a change in laboratory values may occur: abnormally high liver enzyme levels may be found following a blood test. In this case, tell your doctor because this may require additional blood tests.
- Very rare cases of serious skin reactions have been reported. In very rare cases (fewer than 1 in 10,000 people including isolated cases), a skin rash or serious allergic reaction may occur. Stop the treatment immediately and tell your doctor.
- Very rare cases of pain reaction and burning sensation at injection site even diffuse have been reported too.
- In isolated cases, other changes in laboratory values may occur and require blood tests: abnormally low levels of certain blood components (platelets, white blood cells) that could result in nosebleeds or bleeding gums. In this case, tell your doctor.
- Cases of redness of the skin, hot flushes, itching or an abnormally increased heart rate, have been reported.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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.

HPRA Pharmacovigilance Website: www.hpra.ie

5. HOW TO STORE PARACETAMOL 10 mg/ml Solution for Infusion

Keep this medicine out of the sight and reach of children.

Do not use this medicine 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 refrigerate or freeze.

After opening the overwrapping: immediate use is recommended. However, the stability of the product after it has been removed from the overwrapping has been demonstrated for 24 hours.

After dilution in 0.9 % sodium chloride or 5 % dextrose solution, the physicochemical stability of the diluted solution was demonstrated for 2 hours. However, from a microbiological point of view, the product should be used immediately.

Before being administered, the product must be visually inspected. Do not use this medicine if you detect any particles or yellowing.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Paracetamol 10 mg/ml Solution for Infusion contains

The active substance is:

Paracetamol.....10.00 mg for 1 ml of solution for infusion

One 100-ml bag contains 1000 mg paracetamol.

One 50-ml bag contains 500 mg paracetamol.

One 10-ml bag contains 100 mg paracetamol.

The other ingredients are:

Sodium acetate trihydrate, glacial acetic acid and 1N sodium hydroxide (for pH adjustment), water for injections.

What Paracetamol 10 mg/ml Solution for Infusion looks like and contents of the pack

Paracetamol is available as a solution for infusion.

100-ml overwrapped polyolefin bags equipped with an infusion site.

50-ml overwrapped polyolefin bags equipped with a collection site and an infusion site.

10 ml overwrapped polyolefin bags equipped with a collection site.

Marketing authorisation holder

Laboratoire Aguetant
1, rue Alexander Fleming
69007 Lyon
France

Manufacturer

Delpharm Mouvaux
Rue Michel Raillard
59420 Mouvaux
France

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

Belgium: Paracetamol Aguetant 10 mg/ml, solution pour perfusion/oplossing voor infusie/ Infusionslösung.

France: PARACETAMOL AGUETTANT 10 mg/ml, solution pour perfusion

Luxembourg: PARACETAMOL AGUETTANT 10 mg/ml, solution pour perfusion.

Germany: Paracetamol Aguetant 10 mg/ml Infusionslösung.

Ireland/ United Kingdom: Paracetamol 10 mg/ml Solution for Infusion.

This leaflet was last revised in XX/XXXX.

Detailed information on this medicine is available on the MHRA (UK) and HPRA (Eire) web sites.

The following information is intended for healthcare professionals only:

The overwrap should be removed from the bag after checking it is undamaged. Once opened, it should be used immediately.

For single use only. Once opened, the product should be used immediately. Any unused solution must be discarded.

The solution diluted in 0.9 % sodium chloride or 5 % glucose must be visually inspected and should not be used if it is opalescent, or contains visible particles or a precipitate.

The expiry date should be checked.

Check that the bag has no leak, and discard any damaged or partially used bags, or, for 50 and 100 ml bags, those where the hanging hole is not opened.

For 50 and 100 ml bags:

Do not vent and do not connect in series with other infusions.

The protection should be removed from the infusion site.

The infusion set should be connected to the bag.

Patients weighing <10 kg:

- The bag 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 bag and should be given as is or diluted (in a volume from 1 to 9) in a 0.9 % sodium chloride solution or 5 % glucose solution and administered over 15 minute.
- A 5 ml 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.

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