PACKAGE LEAFLET: INFORMATION FOR THE USER

Paracetamol 10 mg/ml solution for infusion
paracetamol
For children and adults from 33 kg up

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, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. WHAT PARACETAMOL IS AND WHAT IT IS USED FOR

This medicine is an analgesic (it relieves pain) and an antipyretic (it lowers fever).

It is indicated for the short-term treatment of moderate pain, especially following surgery, and for the short-term treatment of fever.

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

2. WHAT YOU NEED TO KNOW BEFORE YOU USE PARACETAMOL

Do not use Paracetamol:
- If you are allergic (hypersensitive) to paracetamol or to any of the other ingredients of this medicine.
- If you are allergic (hypersensitive) to propacetamol (another analgesic for infusion and a precursor of paracetamol)
- If you suffer from a severe liver disease

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Paracetamol

- If you suffer from a liver or kidney disease, or from alcohol abuse,
- If you are taking other medicines (including prescription and nonprescription) containing paracetamol,
- In cases of nutrition problems (malnutrition) or dehydration.
- in case of glucose-6-phosphatase dehydrogenase deficiency (may lead to haemolytic anaemia), a blood disease.

During treatment with Paracetamol Accord, tell your doctor straight away if:
- If you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called

metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

It is recommended that a suitable analgesic oral treatment be used as soon as this route of administration is possible.

Other medicines and Paracetamol

Tell your doctor or pharmacist if you are taking or have recently taken any other 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. More check-ups to look at the effect of the anticoagulant might be needed.

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

Please inform your doctor or pharmacist if you are taking flucloxacillin (antiobitic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

Pregnancy and Breastfeeding

If necessary, Paracetamol can be used during pregnancy. You should use the lowest possible dose that reduces your pain and/or your fever and use it for the shortest time possible. Contact your doctor if the pain and/or fever are not reduced or if you need to take the medicine more often.

Paracetamol may be used during breast-feeding.

Driving and using machines
The product does not affect the ability to drive or use machines

Paracetamol contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per unit volume, that is to say essentially “sodium-free”.

3. HOW TO USE PARACETAMOL

Paracetamol will be administered to you by a healthcare professional.

The dose will be individually adjusted by your doctor, based on your weight and general condition.

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

For the 100 ml vials, a 0.8 mm needle (21 gauge needle) has to be used and the stopper vertically perforated at the spot indicated.

If you take more Paracetamol Accord than you should, talk to 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 injury.
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 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 very rare cases (less than 1 out of 10,000 persons, including isolated reports), a serious skin rash or allergic reaction (in the form of anaphylactic shock, urticaria, erythema) may occur. Stop the treatment immediately and inform your doctor.
- In very rare 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.
- Frequent cases of pain and burning sensation at injection site have been reported.
- In not known cases (frequency cannot be estimated from the available data), a serious condition that can make blood more acidic (called metabolic acidosis) have been reported, in patients with severe illness using paracetamol (see section 2)

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via
HPRA Pharmacovigilance
Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE PARACETAMOL

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.

Glass vials: Do not refrigerate or freeze. Store in the original package in order to protect from light.
Plastic bags: Do not store above 25ºC. Do not refrigerate or freeze. Store in the original package in order to protect from light

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

Before administration the product should be visually inspected. Do not use this medicine if you notice any particulate matter and discolouration.

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Paracetamol contains

- The active substance is paracetamol. One ml contains 10 mg paracetamol, this container contains 1000 mg paracetamol in 100 ml.
- The other ingredients are mannitol, sodium dihydrogen phosphate dihydrate, sodium hydroxide (for pH adjustment), povidone K-12 and water for injections.

What Paracetamol looks like and contents of the pack

Paracetamol is a clear, free from visible particles and colourless to slightly brownish solution for infusion.

Paracetamol is supplied in packs of 1, 10, 12 and 20 glass vials of 100 ml or 10, 12 and 50 polyolefin plastic bags of 100 ml with a plastic overpouch.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Accord Healthcare Ireland Ltd,
Euro House,
Euro Business Park,
Little Island,
Cork T45 K857,
Ireland

Manufacturer
Industria Farmaceutica Galenica Senese S.r.l.
Via Cassia Nord, 351
Monteroni d'Arbia (SI) 53014
Italy

This medicine is authorised in the Member States of the European Economic Area and the United Kingdom (Northern Ireland) under the following names:

Name of the Member State	**Name of the medicine**
Austria	Paracetamol Accord 10 mg/ml Infusionslösung
Belgium	Paracetamol Accord 10 mg/ml solution for infusion
Croatia	Paracetamol Accord 10 mg/ml otopina za infuziju
Czech Republic	Paracetamol Accord
Hungary	Paracetamol Accord 10 mg/ml oldatos infúzió
Ireland	Paracetamol 10 mg/ml solution for infusion
Poland	Paracetamol Accord
Portugal	Paracetamol Accord 10 mg/ml solução para perfusão
Romania	Paracetamol Accord 10 mg/ml solutie perfuzabila
Slovenia	Paracetamol Accord 10 mg/ml raztopina za infundiranje
The Netherlands	Paracetamol Accord 10 mg/ml oplossing voor infusie
United Kingdom (Northern Ireland)	Paracetamol 10 mg/ml solution for infusion

This leaflet was last revised in January 2025

The following information is intended for healthcare professionals only:

Below is a summary of the dosage, dilution, administration and storage details for Paracetamol 10 mg/ml solution for infusion. Reference should be made to the Summary of Product Characteristics for full prescribing information.

Intravenous use.
The product is restricted to adults, adolescents and children weighing more than 33 kg.
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 Paracetamol (10 mg/ml) per administration based on upper weight limits of group (ml)****	**Maximum Daily Dose ***
> 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

* 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. No more than 4 doses to be given in 24 hours.

The minimum interval between each administration in patients with severe renal insufficiency must be at least 6 hours.

Renal impairment
In patients with renal impairment, the minimum interval between each administration should be modified according to the following schedule:

Creatinine Clearance	Dosing Interval
cl ≥50 ml/min	4 hours
cl 10-50 ml/min	6 hours
cl <10 ml/min	8 hours

Hepatic impairment
In patients with chronic or compensated active hepatic disease, hepatocellular insufficiency, chronic alcoholism, chronic malnutrition (low reserves of hepatic glutathione), dehydration, Gilbert's syndrome, weighing less than 50 kg:

The maximum daily dose must not exceed 3 g.

There is no contraindication to the use of paracetamol in therapeutic doses in patients with chronic stable liver disease.

Elderly patients
No dose adjustment is usually required in geriatric patients.

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 in intravenous infusion over 15 minutes.