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

You should not be given Paracetamol:
- If you are allergic to paracetamol or any of the other ingredients of this medicine (listed in section 6) or to propacetamol hydrochloride (prodrug of paracetamol).
- If you are allergic to propacetamol (another analgesic 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 containing paracetamol,
- In cases of nutrition problems (malnutrition) or dehydration.

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.

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. More check-ups to look at the effect of the anticoagulant might be needed.

Please inform your doctor or pharmacist if you are taking flucloxacillin (antiobitic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.

Pregnancy and Breastfeeding

If necessary, Paracetamol Accord 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

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 recommended dose is

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	1 g	100 ml	100 ml	3 g

hepatotoxicity				
>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.
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
Intravenous use.

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.

Paracetamol will be given by infusion into one of your veins. The infusion will last approximately 15 minutes.
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 Acccord than you should

In overdose cases, symptoms generally appear within the first 24 hours and comprise: nausea, vomiting, anorexia, pallor, abdominal pain and risk of liver injury. Immediate medical advice should be sought in the event of overdosage, because of the risk of irreversible 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 very rare cases (may affect up to 1 in 10,000 people, including isolated reports), a serious skin rash or allergic reaction may occur. **Stop the treatment** immediately and inform your doctor.
- In rare cases (may affect up to 1 in 1,000 people), 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, 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 medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Paracetamol Accord 10 mg/ml Infusionslösung
Belgium	Paracetamol Accord 10 mg/ml solution for infusion
Bulgaria	Парацетамол Акорд 10 mg/ml инфузионен разтвор
Cyprus	Paracetamol Accord 10 mg/ml solution for infusion
Czech	Paracetamol Accord
Germany	Paracetamol Accord 10 mg/ml Infusionslösung
Croatia	Paracetamol Accord 10 mg/ml otopina za infuziju
Hungary	Paracetamol Accord 10 mg/ml oldatos infúzió
Ireland	Paracetamol 10 mg/ml solution for infusion
Malta	Paracetamol 10 mg/ml solution for infusion
Netherland	Paracetamol Accord 10 mg/ml oplossing voor infusie
Poland	Paracetamol Accord
Romania	Paracetamol Accord 10 mg/ml solutie perfuzabila
Slovenia	Paracetamol Accord 10 mg/ml raztopina za infundiranje
United Kingdom	Paracetamol 10 mg/ml solution for infusion
Spain	Paracetamol Accord10 mg/ml solución para perfusión
Portugal	Paracetamol Accord 10 mg/ml solução para perfusão

This leaflet was last revised in 03/2024.

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 Accord (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
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**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 in intravenous infusion over 15 minutes.