Package leaflet: Information for the patient

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

What is in this leaflet

1. What Paracetamol Fresenius Kabi is and what it is used for
2. What you need to know before you are given Paracetamol Fresenius Kabi
3. How Paracetamol Fresenius Kabi is given
4. Possible side effects
5. How to store Paracetamol Fresenius Kabi
6. Contents of the pack and other information

1. What Paracetamol Fresenius Kabi 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 bottle is restricted to adults, adolescents and children weighing more than 33 kg.

2. What you need to know before you are given Paracetamol Fresenius Kabi

Paracetamol Fresenius Kabi must not be given
- if you are allergic to paracetamol, propacetamol hydrochloride (another pain killer and a precursor of paracetamol) or any of the other ingredients of this medicine (listed in section 6).
- - if you suffer from a severe liver disease.

Warnings and precautions
Talk to your doctor before you are given Paracetamol Fresenius Kabi.

During treatment with Paracetamol Fresenius Kabi, 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).

Take special care with Paracetamol Fresenius Kabi
- if you suffer from a liver or kidney disease, or from alcohol abuse.
- if you suffer from a inherited liver function disorder called Meulengracht Gilbert's syndrome.
- if you suffer from glucose-6-phosphate dehydrogenase deficiency**.**
- if you are taking other medicines containing paracetamol.

- if you suffer from a severe lack of nutrition (malnutrition) or get parenteral nutrition.
- if you suffer from exsiccation.
- talk to your doctor or pharmacist if you are taking or will be taking flucloxacillin. There is a risk of blood and fluid abnormality (high anion gap metabolic acidosis) which occurs when there is an increase in plasma acidity, when paracetamol is used concomitantly with flucloxacillin, particularly in certain groups of patients at risk, such as patients with severe kidney impairment, sepsis or malnutrition, especially if the maximum daily doses of paracetamol are used. High anion gap metabolic acidosis is a serious disease that must have urgent treatment.

Inform your doctor before treatment if any of the above mentioned conditions apply to you.

You should switch to taking pain killing tablets or syrup instead of Paracetamol Fresenius Kabi as soon as is possible.

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

Other medicines and Paracetamol Fresenius Kabi
Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Inform your doctor if you are taking the following medicines:
- Other medicines containing paracetamol. You should not take **other medicines containing paracetamol** if you are getting Paracetamol Fresenius Kabi, in order not to exceed the recommended daily dose (see following section).
- **Probenecid** (a medicine used for the treatment of gout). Your doctor should consider reducing the dose of paracetamol you need, as probenecid increases the levels of paracetamol in your blood.
- **Salicylamide** (another pain killer), as it may increase the levels of paracetamol in your blood and may therefore increase the risk of its toxic effects.
- **Rifampicin, isoniazid (**antibiotics**), barbiturates** (sedatives), **tricyclic antidepressants** and **medicines to treat epileptic fits** (antiepileptics such as carbamazepine, phenytoin, phenobarbital, primidone), as they may reduce the analgesic and antipyretic effects of paracetamol and may increase as well as **alcohol** its liver toxic effects.
- **Chloramphenicol** (an antibiotic), as taking it together with paracetamol may prolong its action.
- **Oral contraceptives** as these may shorten the action of paracetamol.
- **Zidovudine** (a medicine used to treat HIV), as taking it together with paracetamol may lead to an increased risk of a reduction in the number of certain white blood cells (neutropenia). This increases your risk of getting infections.
- O**ral anticoagulants** (substances that slow blood clotting). More check-ups to assess the effect of the anticoagulant might be needed.
- **Flucloxacillin** (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor for advice before you are given this medicine.

Pregnancy
If necessary, Paracetamol Fresenius Kabi 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 receive the medicine more often.

Breast-feeding
Paracetamol Fresenius Kabi may be used during breast-feeding.

Driving and using machines

Paracetamol Fresenius Kabi has no influence on the ability to drive or use machines.

Paracetamol Fresenius Kabi contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially "sodium free".

3. How Paracetamol Fresenius Kabi is given

This medicine is for intravenous (into a vein) use.

Your doctor will administer Paracetamol Fresenius Kabi to you. It is administered by drip (infusion). The dosage will be adjusted individually by your doctor, depending on your weight and general conditions.

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

Your doctor should closely monitor you before the end of the infusion, in order to avoid air entering your vein.

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 Fresenius Kabi 10 mg/ml solution for infusion 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 and with additional risk factors for hepatotoxicity (liver damage)	1 g	100 ml	100 ml	3 g
> 50 kg and no additional risk factors for hepatotoxicity (liver damage)	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.

Renal impairment
In patients with renal insufficiency, the minimum interval between each administration must be modified according to the following scheme:

Creatinine clearance	Administration interval
Clcr ≥ 50 mL/min	4 hours
Clcr 10-50 mL/min	6 hours
Clcr < 10 mL/min	8 hours

Hepatic impairment
In adult patients with chronic liver failure or compensated active liver disease, hepatocellular insufficiency, chronic alcoholism, chronic malnutrition (low hepatic glutathione reserves), dehydration, Gilbert's disease or weighing less than 50 kg, the maximum daily dose must not exceed 3 g.

Older patients
Dose adjustment is not required in the elderly. However, it should be taken into account that renal and/or hepatic insufficiency is more common in patients above 65 years of age.

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.

Paracetamol Fresenius Kabi solution is administered as an infusion (via a drip) into your vein over 15 minutes.
An interval of at least 4 hours must be left between administrations.

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

If you are given more Paracetamol Fresenius Kabi than you should
If you think you were given more Paracetamol Fresenius Kabi 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, loss of appetite, paleness and belly ache. Immediate medical advice should be sought in the event of overdosage, because of the risk of irreversible liver damage.

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.

Common (may affect up to 1 in 10 people)
- Pain and burning sensation at the injection site.

Rare (may affect up to 1 in 1,000 people)
- Changes in laboratory test results (abnormally high levels of liver enzymes found in blood tests). Should this occur, inform your doctor as regular blood tests may be required.

- Low blood pressure (hypotension)
- Feeling unwell (malaise)

Very rare (may affect up to 1 in 10,000 people)
- Reduced number of certain blood cells (platelets, certain white blood cells), possibly leading to bleeding from the nose or gums and an increased risk of infections. Should these occur, inform your doctor, as regular blood tests may be required.
- Allergic reactions ranging from simple skin rash or hives to severe allergic reactions (anaphylactic shock). Possible symptoms include swelling of the face, lips, tongue or other parts of the body and shortness of breath, wheezing or difficulty breathing, temporary narrowing of the airways into the lungs (bronchospasm).
  If you think that Paracetamol Fresenius Kabi is causing an allergic reaction, tell your doctor immediately.
- Very rare cases of serious skin reactions have been reported.

Not known (frequency cannot be estimated from the available data)
- Fast heart beat (tachycardia)
- Redness of the skin, flush, itching
- A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2)

Effects on laboratory tests
Treatment with Paracetamol Fresenius Kabi may alter the results of some laboratory tests for uric acid, as well as of the test for blood glucose.

If any of the side effects gets serious or if you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

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 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 Fresenius Kabi

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 carton or bottle label after 'EXP'. The expiry date refers to the last day of the month.

Keep the bottles in the outer carton in order to protect from light.

Before administration, the product should be inspected visually.
Do not use this medicine if you notice any particles in the solution or discolouration .

Your doctor or the hospital staff will normally store Paracetamol Fresenius Kabi and they are responsible for the quality of the product when it has been opened and if it is not used immediately.

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 protect the environment.

6. Contents of the pack and other information

What Paracetamol Fresenius Kabi contains
- The active substance is paracetamol. Each ml of solution contains 10 mg paracetamol.

Each bottle of 100 ml contains 1000 mg paracetamol.
- The other ingredients are Monothioglycerol, Mannitol (E421), Sodium citrate dihydrate, Acetic acid (for pH-adjustment), Sodium hydroxide (for pH-adjustment) and Water for Injections.

What Paracetamol Fresenius Kabi looks like and contents of the pack

Paracetamol Fresenius Kabi 10 mg/ml solution for infusion is a clear and colourless solution for infusion.

Paracetamol Fresenius Kabi 10 mg/ml solution for infusion is available in 100 ml LDPE bottle.

Pack sizes:
10 bottles
40 bottles

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Fresenius Kabi Deutschland GmbH
Else-Kroener Strasse 1
Bad Homburg v.d.H 61352
Germany

Manufacturer

Fresenius Kabi Polska Sp. z.o.o.
ul. Sienkiewicza 25,
PL-99-300 Kutno,
Poland

This medicine is authorised in the Member States of the European Economic Area under the following names:

Member State	**Name of the medicine**
Austria	Paracetamol Fresenius 10 mg/ml Infusionslösung
Belgium	Paracetamol Fresenius 10 mg/ml oplossing voor infusie Paracetamol Fresenius 10 mg/ml solution pour perfusion Paracetamol Fresenius 10 mg/ml Infusionslösung
Croatia	Paracetamol Fresenius 10 mg/ml otopina za infuziju
Cyprus	PARACETAMOL/FRESENIUS
Czech Republic	Paracetamol Fresenius
Denmark	Paracetamol Kabi
Estonia	Paracetamol Fresenius
Finland	Paracetamol Kabi 10 mg/ml infuusioneste, liuos
France	Paracétamol Fresenius 10 mg/ml, solution pour perfusion

Germany	Paracetamol Fresenius 10 mg/ml Infusionslösung
Greece	PARACETAMOL/FRESENIUS
Hungary	Paracetamol Fresenius 10 mg/ml oldatos infúzió
Iceland	Paracetamol Kabi
Italy	Paracetamolo Fresenius
Latvia	Paracetamol Fresenius 10 mg/ml
Lithuania	Paracetamol Fresenius 10 mg/ml infuzinis tirpalas
Luxembourg	Paracetamol Fresenius 10 mg/ml solution pour perfusion
Malta	Paracetamol Fresenius 10 mg/ml solution for infusion
The Netherlands	Paracetamol Fresenius 10 mg/ml oplossing voor infusie
Norway	Paracetamol Kabi
Poland	Paracetamol Fresenius
Portugal	Paracetamol Fresenius
Romania	Paracetamol Fresenius 10 mg/ml
Slovakia	Paracetamol Fresenius 10 mg/ml
Slovenia	Paracetamol Fresenius 10 mg/ml raztopina za infundiranje
Spain	PARACETAMOL FRESENIUS 10 mg/ml SOLUCION PARA PERFUSION EFG
Sweden	Paracetamol Kabi 10 mg/ml infusionsvätska, lösning

This leaflet was last revised in March 2026.

The following information is intended for healthcare professionals only:

Intravenous use.
The medicinal product is restricted to adults, adolescents and children weighing more than 33 kg.

Handling
For single use only. Any unused solution should be discarded.

Before administration, the product should be visually inspected for any particulate matter and/or discolouration.

After first opening
Chemical and physical in-use stability has been demonstrated for 24 hours at 25°C.
From a microbiological point of view, unless the method of opening precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.

After dilution:
Shelf life after dilution with sodium chloride 9 mg/ml (0.9%) solution or 50 mg/ml glucose (5%) solution or mixture of both: Chemical and physical in-use stability has been demonstrated for 48 hours up to 30 °C.

From a microbiological point of view, unless the method of opening precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.
As for all solutions for infusion presented in bottles, it should be remembered that close monitoring is needed notably at the end of the infusion, regardless of infusion route. This monitoring at the end of the infusion applies particularly for central route infusions, in order to avoid air embolism.

Compatibility
Paracetamol Fresenius Kabi 10 mg/ml solution for infusion can be diluted in sodium chloride 9 mg/ml (0.9%) solution or 50 mg/ml glucose (5%) solution up to one tenth (one volume Paracetamol Fresenius Kabi 10 mg/ml solution for infusion into nine volumes diluent) or a mixture of both.

The diluted solution should be visually inspected and should not be used in the presence of opalescence, visible particulate matter or precipitate.

Disposal
Any unused product or waste material should be disposed of in accordance with local requirements.