Package leaflet: Information for the user

Paracetamol AGmed 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 [Product Name] is and what it is used for
2. What you need to know before you use [Product Name]
3. How to use [Product Name]
4. Possible side effects
5. How to store [Product Name]
6. Contents of the pack and other information

1. What [Product Name] is and what it is used for

This medicine contains the active substance paracetamol, and it is an analgesic (it relieves pain) and an antipyretic (it lowers fever).

The 100 ml vial is restricted to adults, adolescents and children weighing more than 33 kg.
The 50 ml vial is adapted to term newborn infants, infants, toddlers and children weighing less than or equal to 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. What you need to know before you use [Product Name]

Do not use [Product Name]
- if you are allergic to paracetamol or any of the other ingredients of this medicine (listed in section 6),
- if you are allergic to propacetamol (another painkiller for infusion that body converts to paracetamol),
- if you suffer from a severe liver disease.

Warnings and precautions
Talk to your doctor or pharmacist before using [Product Name], if any of these apply to you:
- if you could take analgesic through the mouth (orally) since that is the recommended administration route,
- if you suffer from a liver or kidney disease, or if you drink too much alcohol,
- if you are taking other medicines containing paracetamol,
- in cases of nutrition problems (malnutrition) or dehydration.
- if you have a glucose-6-phosphate dehydrogenase deficiency. This is a disease of the blood.

Other medicines and [Product Name]

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This medicine can affect and be affected by other medicines:
- other medicines that contain paracetamol or propacetamol, so that you do not take more than the recommended daily dose (see section 3 “How to use [Product Name] ”).
- probenecid: a lower dose of paracetamol may be needed.
- salicylamide an anti-inflammatory drug.
- anticoagulants taken by mouth. It may be necessary to control the effect of the anticoagulant medicines that activate liver enzymes: strict control of the paracetamol dose is required in order to avoid liver damage
- flucloxacillin (antibiotic), 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.

[Product Name] with alcohol
Limit the use of alcohol during treatment with this medicine.

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

Pregnancy
If necessary, [Product Name] 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.

Breast-feeding
[Product Name] may be used during breast-feeding.

Driving and using machines
This medicine has no influence on the ability to drive or use machines.

[Product Name] contains sodium
Text for the 50 ml and the 100 ml vials:
This medicinal product contains less than 1 mmol sodium (23mg) per vial, i.e. essentially "sodium free". The 50 ml vial may also be diluted in a 0.9 % sodium chloride solution, this should be taken into consideration.

3. How to use [Product Name]

For intravenous use.
A healthcare professional will give you this medicine by infusion into one of your veins.
The dose will be individually adjusted by your doctor, based on your weight and general condition.

The minimum interval between each administration must be at least 4 hours.
No more than 4 doses to be given in 24 hours.
If you have kidney or liver problems, the doctor may reduce the dose or increase the interval between doses.

This medicine is given into a vein over 15 minutes.
If you have the impression that the effect of [Product Name] is too strong or too weak, talk to your doctor.

If you receive more [Product Name] than you should
Overdose is unlikely as a health care professional will give you this medicine. Your doctor will make sure not to give you doses higher than the recommended dose in your case.

An overdose of [Product Name] is potentially lethal due to irreversible liver damage. There is a risk of serious liver damage even if you feel well.

In order to avoid liver damage it is essential to get medical treatment as early as possible. The shorter the interval between infusion and initiation of treatment with antidote (as few hours as possible), the greater the likelihood that hepatic injury can be prevented.

Talk to a doctor at once if you receive too much of this medicine even if you seem to feel well. This is because too much paracetamol can cause delayed, serious liver damage. The symptoms of liver damage usually appear after a few days.
In overdose cases, the following symptoms may appear within the first 24 hours: nausea, vomiting, anorexia, pallor, abdominal pain..

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

4. Possible side effects

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

Rare (may affect up to 1 in 1,000 persons):
- a malaise,
- a drop in blood pressure
- 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.

Very rare (may affect up to 1 in 10,000 persons, including isolated reports):
- a serious skin rash or allergic reaction. Stop the treatment immediately and inform your doctor.
- Hypersensitivity reaction (skin rash, urticaria, anaphylactic shock)
- 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.

Not known (cannot be estimated from the available data):
- cases of redness of the skin, flushing, itching
- abnormally rapid beating of the heart.
- Cases of pain and burning sensation at injection site.

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 the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Product Name]

Keep this medicine out of the sight and reach of children.
Do not use [Product Name] 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 store above 30 °C. Store in the original package in order to protect from light. Do not refrigerate or freeze.

Do not throw away any medicines via wastewater or household waste. Ask you 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 [Product Name] contains

- The active substance is paracetamol. One ml contains 10 mg paracetamol.
  One vial of 50 ml contains 500 mg paracetamol.
  One vial of 100 ml contains 1000 mg paracetamol.
- The other ingredients are mannitol, cysteine hydrochloride monohydrate, disodium phosphate dihydrate, sodium hydroxide, hydrochloric acid, water for injections.

What [Product Name] looks like and contents of the pack

Clear glass vials of 50 ml and 100 ml, with bromobutyl stopper and aluminium cap.
Pack size: 1, 5, 10, 12, 20, 30, 40, 50, 60 and 100 vials.

[Product Name] is a clear solution.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

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

Czech Republic	Paracetamol AGmed
Slovakia	Paracetamol AGmed 10 mg/ml
Sweden	Paracetamol AGmed

This leaflet was last revised in 2025-03-13

The following information is intended for healthcare professionals only:

A summary of the dosage, dilution, administration and storage details for Paracetamol AGmed 10 mg/ml, solution for infusion. See the Summary of Product Characteristics for full prescribing information.

Intravenous use.

The 100 ml vial is restricted to adults, adolescents and children weighing more than 33 kg.
The 50 ml vial is adapted to term newborn infants, infants, toddlers and children weighing less than or equal to 33 kg.

As for all solutions for infusion presented in glass vials, it should be remembered that close monitoring is needed notably at the end of the infusion, regardless of administration route. This

monitoring at the end of the perfusion applies particularly for central route infusions, in order to avoid air embolism.

Dosage
Information before preparation of the dose

- The minimum interval between each administration must be at least 4 hours.
- No more than 4 doses to be given in 24 hours.
- The paracetamol solution is administered in intravenous infusion over 15 minutes (for more details, see section "Method of administration" below the dosing table).
- The diluted solution should be visually inspected and must not be used in presence of opalescence, visible particulate matter or precipitate.

RISK OF MEDICATION ERRORS
Take care to avoid dosing errors due to confusion between milligram (mg) and milliliter (mL), which could result in accidental overdose and death (see SmPC section 4.2).

Dosage
Dosing based on patient weight (please see the dosing table below)

Patient weight	**Dose per administration**	**Volume per admibnistration**	**Maximum volume of [Product Name] (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 ≤33kg	15 mg/kg	1.5 mL/kg	49.5 mL	60 mg/kg not exceeding 2 g
> 33 kg to ≤50kg	15 mg/kg	1.5 mL/kg	75 mL	60 mg/kg not exceeding 3 g
>50kg 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

*** Pre-term newborn infants**: No safety and efficacy data are available for pre-term newborn infants (see SmPC section 5.2).
****Patients weighing less will require smaller volumes.**
***** 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.

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
≥50 mL/min	4 hours
10-50 mL/min	6 hours
<10 mL/min	8 hours

Hepatic insufficiency
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.
The medicinal product is contraindicated in patients with severe hepatocellular insufficiency.

Method of administration
Patients weighing ≤10 kg:

- The glass vial of [Product Name] 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 vial and could be administered undiluted or diluted (from one to nine volumes diluent) in a 0.9% sodium chloride solution or 5% glucose solution and administered in 15 minutes.
- Use the diluted solution within 4 hours following its preparation (infusion time included).
- A 5 or 10 ml syringe should be used to measure the dose as appropriate for the weight of the child and the desired volume. However, the volume administered to this weight group should never exceed 7.5ml per dose.
- The user should refer to the dosage recommendations in the summary of product characteristics.

To remove solution, use a 0.8 mm needle (21-gauge needle) and vertically perforate the stopper at the spot specifically indicated.
For single use only. Any unused solution should be discarded.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

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 are the responsibility of the user. Note for Guidance on maximum shelf life for sterile products for human use after first opening or following reconstitution.

[Product Name] 50 ml vials can be diluted in a 0.9% sodium chloride solution or 5% glucose solution up to one tenth (one volume [Product Name] into nine volumes diluent).

Shelf life after dilution
For the 50 ml vial, if diluted in 0.9 % sodium chloride or 5 % glucose, the solution should be used immediately. However, if the solution is not used immediately, do not store for more than 4 hours (infusion time included).

Diluted/reconstituted solution: Do not store above 30 °C.