PACKAGE LEAFLET: INFORMATION FOR THE USER

Paracetamol 10 mg/ml Solution for Infusion
For use in adults, adolescents and children weighing more than 33 kg
paracetamol

Read all of this leaflet carefully before you start using this medicine.
- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

CONTAINS PARACETAMOL

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.

Paracetamol 100 ml bag is restricted to patients weighing more than 33 kg.

2. BEFORE YOU USE PARACETAMOL

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

Take special care with Paracetamol
- use a suitable analgesic oral treatment as soon as this administration route is possible.
- 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.

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

Taking or using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription.
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. In this case your doctor will adjust your dose.

A dose reduction should be considered for concomitant treatment with Probenecid.

Salicylamide may cause paracetamol to stay in your body for longer. Inform your doctor if you are taking salicylamide, or other medicines containing salicylamide, as your doctor may need to reduce your dose.

Please inform your doctor or pharmacist if you are taking oral anticoagulants. Closer check-ups of the effect of the anticoagulant might be necessary.

Taking Paracetamol with food and drink
A dose reduction should be considered for patients with alcoholism.

Pregnancy and breast-feeding
Pregnancy
Inform your doctor if you are pregnant. Paracetamol may be used during pregnancy. However, in this case the doctor must evaluate if the treatment is advisable.

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

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

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

Important information about some of the ingredients of Paracetamol
This medicinal product contains 3.56 mmol (82 mg) sodium per dose. To be taken into consideration by patients on a controlled sodium diet.

This medicinal product contains sodium metabisulphite (E223). May rarely cause severe hypersensitivity reactions and bronchospasm.

3. HOW TO USE PARACETAMOL

Dosage

Only for patients >33 kg.

The recommended dose is
Your doctor will determine the correct dose for you exclusively according to your body weight and individual factors.

Method of administration

Intravenous use.

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

If you are given more Paracetamol 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.
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. Because irreversible liver damage may be possible, immediate hospitalisation and treatment with an antidote are necessary. Please inform your doctor if you notice any of these symptoms. Your doctor will assure not to give you doses higher than recommended.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Paracetamol can cause side effects, although not everybody gets them:

- In rare cases (affects 1 to 10 users in 10,000), 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 (affects less than 1 user in 10,000) a serious skin rash or allergic reaction may occur. Stop the treatment immediately and inform your doctor.

- 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.

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.

5. HOW TO STORE PARACETAMOL

Keep out of the reach and sight of children.

Do not use Paracetamol after the expiry date which is stated on the packaging after EXP.
The expiry date refers to the last day of the month.

Do not store above 30°C. Do not refrigerate or freeze.

Aluminium overpouch: Keep the immediate packaging in the outer, aluminium overpouch in order to protect from light.

Plastic overpouch: Keep the immediate packaging in the outer, plastic overpouch and store in the the outer carton in order to protect from light.

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

Note that there is a potential presence of moisture between the bag and the outer sachet due to the sterilisation process, the quality of the product is not impacted.

6. FURTHER INFORMATION

What Paracetamol contains:

- The active substance is paracetamol
- One ml contains 10 mg paracetamol
- Each 100 ml bag contains 1000 mg paracetamol
- The other ingredients are sodium acetate trihydrate, sodium citrate, sodium metabisulphite (E223), mannitol (E421), acetic acid glacial (for pH adjustment) and water for injections.

What Paracetamol looks like and contents of the pack

Bags of 100 ml.

Paracetamol is a clear and colourless or slightly brownish solution.

The medicine is supplied to the hospital in plastic infusion bags fitted with one or two infusion ports closed with rubber stoppers and snap caps. The infusion bags are contained in an aluminium or a plastic overpouch.

Pack sizes: 100 ml bags in packs of 5, 10, 20 or 30 bags.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Teva Pharma B.V.
Computerweg 10
3542 DR Utrecht
The Netherlands

Manufacturer
TEVA Pharmaceutical Works Private Limited Company, H-2100 Gödöllő, Táncsics Mihály út 82, Hungary.
Pharmachemie B.V., Swensweg 5, 2031 GA Haarlem, The Netherlands.

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

Belgium:	Paracetamol Teva 10 mg/ml oplossing voor infusie
Bulgaria:	Paracetamol Teva 10 mg/ml solution for infusion
Czech Republic:	Paracetamol Teva 10 mg/ml, infuzní roztok
Germany:	Paracetamol-ratiopharm 10 mg/ml Infusionslösung
Denmark:	Paracetamol
Greece:	Paracetamol Teva 10 mg/ml Διάλυμα για έγχυση
Spain:	Paracetamol Teva 10 mg/ml solución para perfusion EFG
Finland:	Paracetamol Teva
Hungary:	Paracetamol-Teva 10 mg/ml oldatos infúzió
Ireland:	Paracetamol 10 mg/ml Solution for Infusion
Luxembourg:	Paracetamol Teva 10 mg/ml solution pour perfusion
The Netherlands:	Paracetamol 10 mg/ml Teva, oplossing voor infusie
Norway:	Paracetamol Teva
Poland:	Paracetamol Teva
Romania:	Acamol 10 mg/ml solutie perfuzbila
Sweden:	Paracetamol Teva

This leaflet was last revised in 02/2013

The following information is intended for healthcare professionals only:

HOW TO USE PARACETAMOL

Dosage

Only for patients >33 kg.

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 and ≤ 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

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**
> 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.

Adolescents and adults weighing more than 50 kg:

1000 mg of paracetamol per administration i.e. a 100 ml bag, up to 4 times a day.
Leave an interval of at least 4 hours between administrations.
The maximum dose must not exceed 4000 mg of paracetamol per day, taking into account all the medicines containing paracetamol or propacetamol.

Paracetamol 100 ml bag is restricted to patients weighing more than 33 kg.

Severe renal insufficiency:

It is recommended, giving paracetamol to patients with severe renal impairment (creatinine clearance less than 30 ml/min), to reduce the dose and increase the minimum interval between each administration to 6 hours.

In adults with hepatocellular insufficiency, chronic alcoholism, chronic malnutrition (low reserves of hepatic glutathione) or dehydration, the maximum daily dose must not exceed 3000 mg.

Children weighing more than 33 kg (about 11 years old), adolescent and adults weighing less than 50 kg:

15 mg/kg paracetamol per administration, i.e. 1.5 ml solution per kg, up to 4 times a day. Leave an interval of at least 4 hours between administrations.
The maximum dose must not exceed 60 mg paracetamol per kilo and per day (without exceeding 3000 mg), taking into account all the medicines containing paracetamol or propacetamol.

Do not exceed the stated dose.

Method of administration

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.

Intravenous use.
For single use only. Any unused solution should be discarded.
Paracetamol is administered as a 15-minute intravenous infusion.