

PARAMED®

Paracetamol at 1g/100 ml

Solution for IV infusion, Multilayered bag of 100 ml

Read 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 your 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 side effect gets serious, or if you notice any side effect not listed in this leaflet; please tell your doctor or your pharmacist.

In this leaflet:

1. What PARAMED® is and what it is used for
2. Before you use PARAMED®
3. How to use PARAMED®
4. Possible side effects
5. How to store PARAMED®
6. Further information

1. What PARAMED® is and what it is used for:

Pharmacotherapeutic group:

- Analgesic (softens pain) and antipyretic (lowers fever).

Therapeutic indications:

Short term duration treatment of moderate pain, in particular in postoperative period, and short-term duration treatment of fever, when the intravenous way is clinically justified by the emergency of treating the pain or the hyperthermia and/ or when the other ways of administration are not possible.

2. Before you use PARAMED®:

a. Do not use PARAMED®:

Do never use PARAMED®, in the following cases:

- Hypersensitivity to paracetamol or to propacetamol (another analgesic for infusion, precursor of paracetamol), or to one of the excipients.
- Severe liver disease.

IN CASE OF DOUBT, IT IS NECESSARY TO ASK FOR THE OPINION OF YOUR DOCTOR OR PHARMACIST.

b. Take special care with PARAMED®:

- Use an adapted antalgic treatment by the oral way as soon as this way of administration is possible.
- In case of liver or kidney disease, or of alcohol abuse.
- In case of taking other medicines containing paracetamol.
- In case of nutrition problem (malnutrition) or of dehydration.
- This medicine contains sodium. The rate of sodium is inferior to 1 mmol per 100 ml that is to say « sodium free».

IN CASE OF DOUBT, IT IS NECESSARY TO ASK THE OPINION OF YOUR DOCTOR OR PHARMACIST.

c. Taking other medicines, herbal or dietary supplements:

- This medicine contains paracetamol; it is necessary to take into account in case of taking other medicines based on paracetamol or propacetamol, in order not to exceed the usual recommended dose.

Inform your doctor if you take other medicines containing paracetamol or propacetamol.

PLEASE TELL YOUR DOCTOR OR YOUR PHARMACIST IF YOU ARE TAKING OR HAVE RECENTLY TAKEN ANY OTHER MEDICINES, INCLUDING MEDICINES OBTAINED WITHOUT A PRESCRIPTION.

d. Using PARAMED® with food and drinks:

Nothingness.

e. Pregnancy and breast-feeding:

Pregnancy:

PARAMED® can be used during pregnancy; the doctor should then evaluate the expediency of the treatment.

Breast-feeding:

PARAMED® can be used during breast-feeding.

ASK YOUR DOCTOR OR YOUR PHARMACIST FOR ADVICE BEFORE TAKING ANY MEDICINE.

f. Driving and using machines:

Nothingness.

3. How to use PARAMED®

ALWAYS USE PARAMED® EXACTLY AS YOUR DOCTOR OR PHARMACIST HAS TOLD YOU. YOU SHOULD CHECK WITH YOUR DOCTOR OR YOUR PHARMACIST IF YOU ARE NOT SURE.

PARAMED® is reserved to the adult, the adolescent and to the child weighing more than 33 kg.

Posology:

➤ **Adults and adolescents of more than 50 kg :**

1 g of paracetamol per administration (be one 100 ml of drug solution), up to 4 times per day.

- The maximal dose should not exceed 4 g/day.

➤ **Child of more than 33 kg (about 11 years), adolescents and adults weighing less than 50 kg :**

15 mg/kg of paracetamol per administration (be it 1.5 ml of solution per kg), up to 4 times per day.

- The daily maximal dose should not exceed 60 mg/kg/day (without exceeding 3g).

- In all these cases, respect an interval of at least 4 hours between two administrations.

- You should take into account all the medicines containing paracetamol or propacetamol.

Method of administration:

- Intravenous way: the solution of paracetamol is administered in intravenous infusion of 15 minutes.

- In the child, the volume of the solution to infuse is of 1.5 ml/kg/intake.

CONFORM OBLIGATORILY TO YOUR DOCTOR'S PRESCRIPTIONS.

a. If you take PARAMED® more than you should:

The symptoms generally appear within the first 24 hours and include: nausea, vomiting, anorexia, pallor and risk of liver damage.

CONSULT YOUR DOCTOR OR YOUR PHARMACIST IMMEDIATELY.

b. If you forget to take PARAMED®:

Nothingness.

c. If you stop taking PARAMED®:

Nothingness.

IF YOU HAVE ANY FURTHER QUESTIONS ON THE USE OF THIS MEDICINE, ASK YOUR DOCTOR OR YOUR PHARMACIST.

4. Possible side effects:

Like all medicines, PARAMED® can cause some side effects, although not everyone gets them.

- In rare cases (>1/10000 and <1/1000): discomfort, lowering of blood pressure or biological modifications: abnormally elevated rates of hepatic enzymes.

- In very rare cases (<1/10000): cutaneous eruption or a severe allergic reaction. You should stop the treatment immediately and alert the doctor.

- Sensation of pain and burning at the point of injection that can be related to a very quick initial rate of infusion, redness of the skin, hot flushes, itching and abnormal increase of the cardiac rhythm have been reported.

IF ANY SIDE EFFECT GETS SERIOUS, OR IF YOU NOTICE ANY SIDE EFFECT NOT LISTED IN THIS LEAFLET, PLEASE TELL YOUR DOCTOR OR YOUR PHARMACIST.

5. How to store PARAMED®

- Before opening the over package: store at less than 30°C.

- After opening the over package: an immediate use is recommended.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of no longer required medicines. These measures will help in protecting the environment.

6. Further information:

a. What PARAMED® contains:

- The drug substance is Paracetamol at 1g /100 ml.

- The other ingredients are: glucose monohydrate, glacial acetic acid, sodium acetate trihydrate, sodium citrate dihydrate, sodium hydroxide and/or hydrochloric acid, water for injections.

b. What PARAMED® looks like and contents of the pack:

PARAMED® is a solution for IV infusion packaged in multilayered bags of 100 ml with an aluminum over-packaging. Box of 6 bags.

c. Marketing Authorization Holder and Manufacturer:



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d. This leaflet was last approved in {01/2022} ; version number {xx}.

e. Registration number in Lebanon: xxxxxxxx

THIS IS A MEDICINE

- This is a product that affects your health and not following the method of administration puts you at risk.
- Follow carefully the doctor's prescription, the directions for use and the pharmacist's advice.
- The doctor and the pharmacist are the experts on the medicine and know its benefits and risks.
- Do not stop taking the medicine on your own.
- Do not renew the supply of this medicine without consulting the doctor.
- Keep medicines away from children.

COUNCIL OF ARAB HEALTH MINISTERS

Leaflet code