

PARACETAMOL NORMON 10 mg/ml solution for infusion

Read this leaflet carefully before using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any question, consult your doctor or pharmacist.
- This medicine has been prescribed to you personally and you must not give it to others. It can harm them, even if the symptoms are the same as yours.
- If you think any of the adverse effects you suffer are severe or if you notice any adverse effects not mentioned in this leaflet, inform your doctor or pharmacist.

This leaflet contains:

1. WHAT paracetamol NORMON 10 mg/ml solution for infusion IS AND WHEN IT IS USED FOR
2. BEFORE USING paracetamol NORMON 10 mg/ml solution for infusion
3. HOW TO USE paracetamol NORMON 10 mg/ml solution for infusion
4. POSSIBLE SIDE EFFECTS
5. HOW TO STORE paracetamol NORMON 10 mg/ml solution for infusion
6. ADDITIONAL INFORMATION

1. WHAT paracetamol NORMON 10 mg/ml solution for infusion IS AND WHEN IT IS USED FOR

This product belongs to a group of medicines called "analgaesics" and "antipyretics" that relieve pain and reduce fever.

Paracetamol NORMON 10 mg/ml is indicated for the short-treatment of moderate pain, particularly following surgery, and for the short-term treatment of fever, when intravenous administration is necessary for urgent treatment of pain or fever and/or when other administration routes are unfeasible.

2. BEFORE USING paracetamol NORMON 10 mg/ml solution for infusion

• Do not use paracetamol NORMON 10 mg/ml:

- If you are allergic (hypersensitive) to paracetamol or any of the other ingredients of paracetamol NORMON 10 mg/ml solution for infusion.
- If you are allergic (hypersensitive) to propacetamol (another analgaesic for infusion and paracetamol precursor).
- If you suffer from serious liver disease.

• Take special care with paracetamol NORMON 10 mg/ml:

- If you suffer from any liver disease.
- If you suffer from serious kidney disease.
- If you suffer from chronic alcoholism.
- If you suffer from chronic malnutrition.
- If you are dehydrated.

Before the treatment tell your doctor if any of the abovementioned conditions is applicable to you.

Use an appropriate oral analgaesic treatment as soon as this administration route is possible.

• Using other medicines:

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

This medicine contains paracetamol, which should be considered when taking other medicines containing paracetamol or propacetamol, to not exceed the recommended daily dose (see Section 3. How to use). Tell your doctor if you are taking other medicines containing paracetamol or propacetamol.

A reduced dose should be considered in concomitant treatment with probenecid (medicine for the treatment of gout).

Tell your doctor or pharmacist if you are taking oral anticoagulants. You may need to have more frequent monitoring of the anticoagulant effect.

• Pregnancy and breastfeeding:

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

Paracetamol should be used in pregnancy only after careful assessment of the benefit-risk ratio. In this case, the recommended dosage and duration should be accurately followed.

Paracetamol NORMON 10 mg/ml can be used during breastfeeding.

• Important information concerning some of the ingredients of paracetamol NORMON 10 mg/ml:

Patients on sodium-low diets must note that this medicine contains 2.415 mg of sodium per millilitre.

3. HOW TO USE paracetamol NORMON 10 mg/ml solution for infusion

Paracetamol NORMON 10 mg/ml is a solution administered intravenously, as infusion always for at least 15 minutes.

Careful monitoring is required before performing the infusion.

The usual dose is:

Always take paracetamol exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Adolescents and adults over 50 kg weight:

1 g of paracetamol per administration, i.e., a 100 ml bag, up to four times a day.

Leave at least 4 hours between each administration.

The maximum dose must not exceed 4 g of paracetamol a day, including all medicines containing paracetamol or propacetamol.

Children over 33 kg weight (about 11 years), adolescents, and adults of less than 50 kg in weight:

15 mg/kg of paracetamol per administration, i.e., 1.5 ml of solution per kg, up to four times a day.

Leave at least 4 hours between each administration.

The maximum dose must not exceed 60 mg of paracetamol per kg/day (without exceeding 3 g), including all medicines containing paracetamol or propacetamol.

Children over 10 kg and less than 33 kg of weight:

15 mg/kg of paracetamol per administration, i.e., 1.5 ml of solution per kg, up to four times a day.

Leave at least 4 hours between each administration.

The maximum dose must not exceed 60 mg of paracetamol per kg/day (without exceeding 2 g), including all medicines containing paracetamol or propacetamol.

Full-term newborns, infants and children of less than 10 kg of weight (up to about 1 year):

7.5 mg/kg of paracetamol per administration, i.e., 0.75 ml of solution per kg, up to four times a day.

Leave at least 4 hours between each administration.

The maximum daily dose must not exceed 30 mg of paracetamol per kg/day, including all medicines containing paracetamol or propacetamol.

No safety and efficacy data are available from premature children.

Method of administration:

The solution of paracetamol is administered as an intravenous infusion always for at least 15 minutes.

In children, the volume of solution infused should be 1.5 ml per kg per administration.

Patients with severe kidney disease:

It is recommended to extend the time between each administration to 6 hours.

If you feel that the effect of paracetamol NORMON 10 mg/ml is too strong or too weak, consult your doctor or pharmacist.

If you use more paracetamol NORMON 10 mg/ml solution for infusion than the recommended dose:

In case of overdose or accidental ingestion, contact your doctor at once. Tell them the medicine and amount taken.

Doses higher than recommended can cause highly severe liver lesions.

The most common symptoms in case of overdose are: nausea, vomiting, anorexia (lack of appetite), pallor, abdominal pain and signs of risk of liver disorders.

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 NORMON 10 mg/ml can cause side effects, although by no means for every patient.

The following side effects have been reported:

- Rare (more than 1 in 10,000, less than 1 in 1,000 patients.)
- Malaise.
- Reduced blood pressure.
- Changes in liver enzyme levels (transaminases).
- Very rare (less than 1 in 10,000 patients, including isolated cases)
- Various allergic reactions (from simple skin rash or itching to generalised allergic reaction). If this occurs, discontinue treatment immediately and tell your doctor.
- Local reactions at the site of administration: pain, phlebitis, erythema.
- Reduced blood platelet levels, causing possible bleeding, such as of the nose or gums. If this occurs, consult your doctor.
- Cases of skin reddening, flushing, itching and abnormally fast heart rhythm.

If you notice any serious side effects, or any that are not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE paracetamol NORMON 10 mg/ml solution for infusion

Keep it out of the reach and sight of children.

Do not store at a temperature above 25°C. Protect from humidity.

Store in the original package to protect from light.

Do not refrigerate or freeze.

Do not use paracetamol NORMON 10 mg/ml after the expiry date stated on the package after "EXP". The expiry date refers to the last day of the month.

Do not use paracetamol NORMON 10 mg/ml if you see any particle or if the solution is not colourless or practically colourless.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist for disposal of the packages and medicines you do not need. These measures will help to protect the environment.

6. ADDITIONAL INFORMATION**Composition of paracetamol NORMON 10 mg/ml solution for infusion**

The active ingredient is paracetamol. Each ml contains 10 mg of paracetamol.

The other components (excipients) are: sodium hydrochloride, sodium acetate, disodium edetate, hydrochloric acid

or sodium hydroxide and water for injection.

Paracetamol NORMON 10 mg/ml solution for infusion appearance and contents of the package

Paracetamol NORMON 10 mg/ml is presented in the form of solution for infusion. The solution is transparent, colourless or practically colourless.

Paracetamol NORMON 10 mg/ml solution for infusion is presented in 100 ml bags.

Marketing authorisation holder and manufacturer:

LABORATORIOS NORMON, S.A.

Ronda de Valdecarrizo, 6 - 28760 –Tres Cantos- MADRID (SPAIN).

OTHER PRESENTATIONS

PARACETAMOL NORMON 500 mg TABLETS

PARACETAMOL NORMON 650 mg TABLETS

This patient information leaflet has been reviewed in February 2012