Package leaflet: information for the patient
Paracetamol ALTAN 10 mg/ml solution for infusion

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.
- 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 nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Paracetamol ALTAN is and what it is used for

This medicine is an analgesic (it relieves pain) and an antipyretic (it lowers fever).
The 100 ml bag is restricted to adults, adolescents and children weighing more than 33 kg.
The 50 ml bag is adapted to term newborn infants, infants, toddlers and children weighing less than 33 kg.

Paracetamol ALTAN 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 take use Paracetamol ALTAN

Do not use Paracetamol ALTAN

• if you are allergic (hypersensitive) to paracetamol or to any of the other ingredients of Paracetamol ALTAN
• if you are allergic (hypersensitive) to propacetamol (another analgesic for infusion and a precursor of paracetamol).
• if you suffer from a severe liver disease.

Warnings and precautions

• 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.

Other medicines and Paracetamol ALTAN

Do not give with any other paracetamol-containing medicines. 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.
A dose reduction should be considered for concomitant treatment with Probenecid.Please inform your doctor or pharmacist if you are taking oral anticoagulants. Closer check-ups of the effect of the anticoagulant might be necessary.

Please inform your doctor or pharmacist if you are taking:
-flucloxacillin (antiobitic), 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.

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

Pregnancy and breast-feeding

Pregnancy
Inform your doctor if you are pregnant.
If necessary, Paracetamol ALTAN can be used during pregnancy. However, in this case the doctor must evaluate if the treatment is advisable. 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. Ask your doctor or pharmacist for advice before taking any medicine.

Breast-feeding
If necessary, Paracetamol ALTAN can 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 ALTAN 10 mg/ml, solution for infusion

Paracetamol ALTAN contains 39.7 mg sodium per 50 mL and 79.4 mg sodium per 100 mL, which should be taken into account by patients on a low salt diet.

This medicine contains glucose. Patients with diabetes mellitus must take into account that this medicine contains 1.65 g glucose per 50 mL and 3.30 g glucose per 100 mL.

3. How to use Paracetamol ALTAN

You should not be given more medicine than the label says. Do not exceed the stated dose.
Intravenous use.
Paracetamol ALTAN will be administered to you by a healthcare professional by infusion into one of your veins.
The dose will be individually adjusted by your doctor, based on your weight and general condition.
Check patient’s weight before administration.
The 100 ml bag is restricted to adults, adolescents and children weighing more than 33 kg.
The 50 ml bag is adapted to term newborn infants, infants, toddlers and children weighing less than 33 kg.

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 ALTAN (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 2g
> 33 kg to ≤50kg	15 mg/kg	1.5 mL/kg	75 mL	60 mg/kg not exceeding 3g
>50kg with additional risk factors for hepatotoxicity	1 g	100 mL	100 mL	3 g
> 50 kg and no additional risk factors for hepatotoxicity	1g	100 mL	100 mL	4 g

* **Pre-term newborn infants:** No safety and efficacy data are available for pre-term newborn.
****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.
***** 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.

The paracetamol solution is administered in intravenous infusion over 15 minutes.
If you have the impression that the effect of Paracetamol ALTAN 10 mg/ml, solution for infusion is too strong or too weak, talk to your doctor.
If you or your child use more Paracetamol ALTAN 10mg/ml, solution for infusion than if you or your child should use, talk to a doctor at once if you or your child take too much of this medicine even if you or your child seem feel well. This is because too much paracetamol can cause delayed, serious liver damage.
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.
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 ALTAN can cause side effects, although not everybody gets them.

• In rare cases (more than 1 out of 10,000 persons and less than 1 out of 1,000 persons), 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 (less than 1 out of 10,000 persons, including isolated reports), 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.

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Paracetamol ALTAN

Keep this medicine out of the sight and reach of children.

Do not store above 25ºC.
Keep the bag in the protective overwrap in order to protect from light and excessive water loss.
After opening the overwrapping immediate use is recommended

Do not use Paracetamol ALTAN after the expiration date indicated on the package. The expiry date is the last day of that month.

Do not use Paracetamol ALTAN if you observe the presence of particles or a change to the colour of the solution.
For single use only, discard any unused portion. From a microbiological point of view, unless the method of opening precludes the risk of microbial contamination, the product must be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to throw away medicines and containers you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Paracetamol ALTAN contains

- The active substance is paracetamol. Each ml of solution for infusion contains 10 mg paracetamol.
- The other ingredients are glucose monohydrate, acetic acid, sodium acetate trihydrate, sodium citrate dehydrate, sodium hydroxide, hydrochloric acid and water for injections.

What Paracetamol ALTAN looks like and contents of the pack

Paracetamol ALTAN is colourless or faintly straw-brown coloured solution packaged in PVC bags of 50 or 100 ml with a metal overwrapp. It is presented in packs containing 10 bags, 12 bags of 50 or 100 ml or 50 bags of 100 ml.

Not all pack sizes or presentation may be marketed.

Marketing authorisation holder and manufacturer

Marketing Authorisation Holder:
Altan Pharma Limited
The Lennox Building, 50 South Richmond Street
Dublin 2, D02FK02
Ireland

Manufacturer:
Altan Pharmaceuticals, S.A.
Pol. Ind. De Bernedo s/n
01118 Bernedo (Álava) - Spain

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder:

This leaflet was last revised in: 05/2022

INFORMATION FOR HEALTH PROFESSIONALS
Below is a summary of the dosage, dilution, administration and storage details for Paracetamol ALTAN 10 mg/ml, solution for infusion. Reference should be made to the Summary of Product Characteristics for full prescribing information.

Intravenous use.

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

For the 50ml and 100ml bag, close monitoring is needed before the end of infusion.

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 ALTAN (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	1g	100mL	100mL	4g

* **Pre-term newborn infants:** No safety and efficacy data are available for pre-term newborn.
**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.
***** 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.

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.

The paracetamol solution is administered in intravenous infusion over 15 minutes.

Patients weighing ≤10 kg:
• The bag of Paracetamol ALTAN 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 bag and diluted in a 0.9% sodium chloride solution or 5% glucose solution up to one tenth (one volume Paracetamol ALTAN into nine volumes diluent) and administered over 15 minute.
• 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, this should never exceed 7.5ml per dose
• The user should be referred to the product information for dosing guidelines.
For the 50ml and 100ml bags, a 0.8 mm needle (21 gauge needle) has to be used and the stopper vertically perforated at the spot specifically indicated.
It can also be diluted in 0.9% sodium chloride or 5% glucose up to one tenth (one volume Paracetamol ALTAN into nine volumes diluent).
The diluted solution should be visually inspected and must not be used if opalescence, visible particulate matter or precipitate are found.