MODULE-1
ADMINISTRATIVE INFORMATION FOR AXAPARA

PATIENT INFORMATION LEAFLET (PIL)

Read this entire leaflet carefully before you starts taking 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. 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.

What is in this leaflet:

1. WHAT AXAPARA IS AND WHAT IT IS USED FOR

This medicine 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 new born infants, infants, toddlers and children weighing less than 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. BEFORE YOU USE AXAPARA

- if you are allergic (hypersensitive) to paracetamol or to any of the other ingredients of Paracetamol Intravenous Infusion.
- 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 AXAPARA

• 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

Do not give anything else containing paracetamol while giving this medicine. 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 or have recently taken any other medicines, even those not prescribed.

Pregnancy and breast-feeding

Pregnancy

Inform your doctor if you are pregnant. Paracetamol Intravenous Infusion 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 Intravenous Infusion 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 Intravenous Infusion

This medicinal product contains less than 1 mmol sodium (23mg) per 100 ml of Paracetamol Intravenous Infusion, i.e. essentially "sodium free".

3. HOW TO USE AXAPARA

You should not be given more medicine than the label says. Do not exceed the stated dose.

Intravenous use.

Paracetamol Intravenous Infusion 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.

The 100 ml vial is restricted to adults, adolescents and children weighing more than 33 kg.

The 50 ml vial is adapted to term new born 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 Intravenous infusion 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	1.5mL/kg	49.5 mL	60mg/kg not exceeding 2g
> 33 kg to ≤50kg	15 mg/kg	1.5mL/kg	75 mL	60mg/kg not exceeding 3g
>50 kg with additional risk factors for hepatotoxicity	1g	100mL	100mL	3g
> 50 kg and no additional risk factors for hepatotoxicity	1g	100mL	100mL	4g

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

**** 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 Intravenous infusion is too strong or too weak, talk to your doctor.

If you or your child use more Paracetamol Intravenous 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 Intravenous infusion 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.

5. HOW TO STORE AXAPARA

Keep out of the reach and sight of children.

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

Store below 30ºC. Protect from light. Do not refrigerate or freeze.

For the 50ml vial, after dilution in 0.9% sodium chloride or 5% glucose: do not store for more than 1 hour (infusion time included).

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

For single use only. The product should be used immediately after opening. Any unused solution should be discarded.

6. FURTHER INFORMATION

What **AXAPARA** contains

- The active substance is paracetamol.
- The other ingredients are Mannitol BP, Disodium hydrogen phosphate Dihydrate BP, Sodium hydroxide BP, Hydrochloric acid BP & Water for Injection BP.

What AXAPARA looks like and contents of the pack

A clear, colourless solution.

Pack: 100 ml LDPE bottle packed in a unit carton, along with the pack insert.