

Package leaflet: Information for the user

Paralink 10 mg/ml Solution for Infusion Paracetamol

Read all of this leaflet carefully before you are given 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.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Paralink is and what it is used for
2. What you need to know before is administered to you
3. How Paralink is administered to you
4. Possible side effects
5. How to store Paralink
6. Contents of the pack and other information

1. WHAT PARALINK IS AND WHAT IT IS USED FOR

Paralink contains the active substance paracetamol, an analgesic (it relieves pain) and an antipyretic (it lowers fever).

Contains paracetamol

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

The 50 ml vial is restricted to term newborn infants, infants, toddlers and children weighing less than 33 kg.

Take care not to exceed the maximum dose of paracetamol if you are using other medicines containing paracetamol. Do not exceed the recommended dose because of the risk of irreversible liver damage, immediately contact your doctor even if you feel well if too much Paralink has been administered to you.

This medicine is given by intravenous infusion directly into a vein. It is used for

- short-term treatment of moderate pain, especially following surgery
- short-term treatment of fever.

2. WHAT YOU NEED TO KNOW BEFORE PARALINK IS ADMINISTERED TO YOU

Do not use Paralink

- if you are allergic to paracetamol or to any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to propacetamol (another analgesic and related to paracetamol)
- if you suffer from severe liver disease

Warnings and precautions

- Do not exceed the recommended dose. Doses higher than those recommended entail the risk of very serious liver damage. Symptoms of liver damage are not usually seen until 2 days, and up to a maximum of 4-6 days, after administration
- Take care not to exceed the maximum dose of paracetamol if you are using other medicines containing paracetamol (see section 2 “Other medicines and Paralink”)
- Dosage adjustment may be necessary in the following cases:
 - liver or kidney disease
 - alcohol abuse
 - nutrition problems (malnutrition)
 - dehydration.

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

Use a suitable analgesic for oral use (via the mouth) as soon as this is possible.

Other medicines and Paralink

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

This medicine contains paracetamol. This must be taken into account if you are using other medicines containing paracetamol, in order not to exceed the recommended daily dose (see section 3 “How Paralink is administered to you”). Inform your doctor if you are taking other medicines containing paracetamol.

It is very important to tell your doctor if you are taking any of the following medicines. These medicines and Paralink can interfere with each other:

- Probenecid (medicine used to treat gout): a lower dose of paracetamol may be needed
- Salicylamide (anti-inflammatory drug)
- Anticoagulants taken via the mouth (such as warfarin, acenocoumarol). It may be necessary to control the effect of the anticoagulant.

Paralink with food, drink and alcohol

Limit the use of alcohol during treatment with this medicine.

Pregnancy and breast-feeding

Inform your doctor if you are pregnant. Paralink may be used during pregnancy. However, in this case the doctor must evaluate if the treatment is advisable.

Paralink may be used during breast-feeding.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Paralink has no influence on the ability to drive and use machines.

Important information about some of the ingredients of Paralink

This medicinal product contains less than 1 mmol sodium (23 mg) per 100 ml, i.e. essentially 'sodium free'.

3. HOW PARALINK IS ADMINISTERED TO YOU

Intravenous use.

The 50 ml vial is restricted 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 Paralink (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	7.5mL	30 mg/kg
> 10 kg to ≤33kg	15 mg/kg	1.5mL/kg	49.5mL	60mg/kg not exceeding 2g
> 33 kg to ≤50kg	15 mg/kg	1.5mL/kg	75 mL	60mg/kg not exceeding 3g
>50kg with additional risk factors for hepatotoxicity	1g	100mL	100mL	3g
> 50 kg and no additional risk factors for hepatotoxicity	1 g	100mL	100mL	4g

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

**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.

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.

This medicine is given as a slow infusion (drip) into a vein over 15 minutes.

For single use only.

Any unused solution should be discarded.

Patients weighing ≤ 10 kg:

- The glass vial of Paralink 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 vial and diluted in a 0.9% sodium chloride solution or 5% glucose solution up to one tenth (one volume Paralink into nine volumes diluent) and administered over 15 minute. In this case, use the diluted solution within the hour following its preparation (infusion time included).

Text for the 50ml and 100ml vials:

To remove solution, use a 0.8 mm needle (21 gauge needle) and vertically perforate the stopper at the spot specifically indicated.

Text for the 50ml vial:

Paralink of 50ml vial can also be diluted in a 0.9% sodium chloride solution or 5% glucose solution up to one tenth (one volume Paralink into nine volumes diluent).

Text for the 50ml and 100ml vials:

As for all solutions for infusion presented in glass vials, it should be remembered that close monitoring is needed notably at the end of the infusion, regardless of administration route. This monitoring at the end of the perfusion applies particularly for central route infusion, in order to avoid air embolism.

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 Paralink than you should

Because of the risk of irreversible liver damage, immediately contact your doctor even if you feel well if too much Paralink has been administered to you. In overdose cases, symptoms generally appear within the first 24 hours. These symptoms comprise of nausea (feeling sick), vomiting, anorexia, a pale appearance to the skin and abdominal pain.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Rare side effects: may affect up to 1 in 1,000 people

The following may occur:

- a drop in blood pressure

- changes in laboratory test results:- abnormally high levels of liver enzymes found during blood checks. Regular blood checks may be required
- feeling generally unwell and run down.

Very rare side effects: may affect up to 1 in 10,000 people

The following may occur:

- a serious skin rash or allergic reaction. 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 blood cells) can occur, possibly leading to bleeding from the nose or gums. Should this occur, please inform your doctor.

Cases of skin redness, flushing, itching and abnormally rapid heart rate have been reported.

As with all injectable medicinal products the patient may experience local reactions (such as pain and burning sensation) at the injection site.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE PARALINK

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the vial and carton after EXP. The expiry date refers to the last day of that month.

No special storage conditions required. Keep the vial in the original carton, in order to protect from light. Do not refrigerate or freeze.

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

Shelf life after first opening: Use immediately after opening

Before administration, the product should be inspected visually. Do not use Paralink if you notice any particulate matter and discolouration. These are visible signs of deterioration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Paralink contains

- The active substance is paracetamol. One ml contains 10 mg paracetamol. Each vial (100 ml) contains 1000 mg paracetamol.
- The other ingredients are mannitol, disodium phosphate dihydrate, cysteine hydrochloride monohydrate, sodium hydroxide (4%) (for pH-adjustment), hydrochloric acid (37%) (for pH-adjustment) and water for injections.

What Paralink looks like and contents of the pack

Paralink is a solution for infusion.

It is a clear, slightly yellowish solution which is contained in a colourless glass vial with a rubber stopper and sealed with an aluminium cap.

The vials are packed in carton boxes.

50 ml: each box contains 10 (10 x 1) vials

100 ml: each box contains 1 or 10 (10 x 1) vials.

Not all pack sizes or presentation may be marketed.

Marketing Authorisation Holder

Ricesteele Manufacturing Ltd., Cookstown industrial Estate, Tallaght, Dublin, D24TP 60

Product Authorisation Number

PA 0095/007/011

Manufacturer

SM Farmaceutici SRL
Zona industriale
85050 TITO – POTENZA
Italy

OR

Neogen Developments N.V.
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This medicinal product is authorised in the Member States of the EEA under the following names:

Germany (RMS):	Paracetamol Hikma 10 mg/ml Infusionslösung
Belgium:	Paracetamol Teva 10mg/ml oplossing voor infusie
Finland:	Wegmal 10mg/ml infuusioneste, liuos
Italy:	Paracetamolo Molteni
Ireland:	Paralink 10mg/ml solution for infusion
Luxembourg:	Paracetamol Teva 10mg/ml solution pour perfusion
Poland:	Paracetamol Polpharma

This leaflet was last approved in August 2015