## Paralink SIX PLUS PARACETAMOL 250mg/5ml Oral Solution

## Please read all of this leaflet carefully before you take this medicine or give it to a child.

- Keep this leaflet. You may need to read it again
- If you need more information or advice, please ask your doctor or pharmacist
- You must contact your doctor if you or your child's symptoms get worse or do not improve If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### In this leaflet:

- 1. What Paralink Six Plus is and what is it used for
- 2. Before you take or give Paralink Six Plus
- 3. How to take or give Paralink Six Plus
- 4. Possible side effects
- 5. How to store Paralink Six Plus
- 6. Further information.

## 1. What Paralink Six Plus is and what is it used for

Paralink Six Plus Paracetamol 250mg/5ml Oral Solution is a strawberry flavoured, colourless/straw coloured, sugar-free, solution which contains paracetamol as the active ingredient. Paralink Six Plus Paracetamol 250mg/5ml Oral Solution is used for the treatment of mild to moderate pain, including headache, migraine, nerve pain (neuralgia), toothache and pain associated with teething. It is also used to relieve the symptoms of colds and flu and to lower a high temperature (fever).

It is suitable for children aged 6 years and over.

### 2. Before you take or give Paralink Six Plus

### DO NOT USE Paralink Six Plus if:

- You or your child are allergic to paracetamol or to any of the other ingredients listed (see ingredients list in section 6)
- You or your child have 'hereditary fructose intolerance', a condition where some sugars can't be broken down
- You or your child are taking any other paracetamol containing medicines.

### TAKE SPECIAL CARE, speak to your doctor or pharmacist before using Paralink Six Plus if:

• You or your child has kidney or liver problems.

### Taking other medicines:

Paralink Six Plus can affect some other medicines you or your child may be taking. Always tell your doctor or pharmacist about all the medicines you or your child are using. This means medicines you have bought yourself as well as those you have on prescription from your doctor.

Make sure your pharmacist knows if you or your child are taking or have recently taken any other medicines including:

- metoclopramide and domperidone used to treat feeling and being sick (nausea and vomiting) colestyramine, used to treat high cholesterol
- drugs that thin the blood (anticoagulants) such as warfarin drugs to treat epilepsy (anticonvulsants)

- oral contraceptives (the 'pill')
- other paracetamol containing medicines.
- flucloxacillin (antibiotic), 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.

## Other special warnings:

- Contains Paracetamol. Do not use with any other paracetamol containing products
- Immediate medical advice should be sought in the event of an overdose, because of the risk of irreversible liver damage
- Prolonged use, without medical supervision, can be harmful
- Maximum duration of continued use without medical advice is 3 days
- If symptoms persist, consult your doctor
- Do not exceed the stated dose.

## If adults take this medicine:

The following warnings also apply if you are an adult taking this medicine:

- If you drink large amounts of alcohol, you may be more prone to the side effects of paracetamol, and the dangerous effects of a paracetamol overdose
- Ask your doctor or pharmacist for advice before taking this medicine if you are pregnant, think you might be pregnant or are breast feeding
- If necessary, Paralink Six Plus can be used during pregnancy. 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 or midwife if the pain and/or fever are not reduced or if you need to take the medicine more often
- You can use this medicine while you are taking oral contraceptives ('the pill'), but it may not work as well on your pain or fever.

## Important information about some of the ingredients

- Contains propylene glycol which may cause alcohol-like effects
- Contains sorbitol (E420) and maltitol (E965). If you or your child has an intolerance to some sugars, contact your doctor before taking or giving this medicine
- Sorbitol may have a mild laxative effect; the calorific value of sorbitol is 2.6Kcal/g
- Contains the preservatives ethyl (E214), propyl (E216) and methyl (E218) parahydroxybenzoate which may cause allergic reactions which could be possibly delayed.

## 3. How to take or give Paralink Six Plus

Check the tables below to see how much of the medicine to use.

- For oral use only
- Never take or give more medicine than shown in the table
- Always use the syringe supplied with the pack
- Do not take or give with any other paracetamol-containing products.

The usual dose is as follows:

Child's Age	How Much	How often (in 24 hours)
6 – 8 years	5ml	4 times
8 – 10 years	7.5ml	4 times
10 – 12 years	10ml	4 times
• Do not take or give more than 4 doses in any 24 hour period		
<ul> <li>Leave at least 4 hours between doses</li> </ul>		
• Do not take or give this medicine for more than 3 days without speaking		
to your doctor or pharmacist		
<ul> <li>Do not give to children under the age of 6 years.</li> </ul>		
Children aged 12 – 16 years:	10 – 15ml	up to 4 times a day.
Adults and children over 16	10 – 20ml	up to 4 times a day.

# years:

# If anyone has taken too much Paralink Six Plus:

# Immediate medical advice should be sought in the event of an overdose, because of the risk of irreversible liver damage.

Take your medicine or the pack with you so that the doctor knows what you have taken.

# If you forget to take or give a dose of Paralink Six Plus:

If you or your child missed a dose, don't worry; take or give the next dose when needed, provided that the last dose was at least 4 hours ago. Do not take or give a double dose (2 doses at the same time) to make up for a missed dose.

# If you are not sure how to take or give this medicine and would like further information, then please contact your doctor or pharmacist as soon as possible.

# 4. Possible side effects

Like all medicines Paralink Six Plus may sometimes cause side effects, although, these don't affect everyone and are usually mild.

# STOP using Paralink Six Plus and seek immediate medical help if you notice the following rare but serious symptoms:

- Allergic (hypersensitivity) reactions including skin rash. Very rare cases of serious skin reactions have been reported
- Unexpected bruising or bleeding, sore throat, infections or fever, pale skin and weakness or breathlessness. These can be a sign of severe blood disorders (thrombocytopoenia and agranulocytosis).

# Other side effects may include:

- Liver problems which may cause yellowing of the skin or whites of the eyes (jaundice)
- Kidney problems.

## **Reporting of side effects**

If you or your child get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2;

Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Paralink Six Plus

## Keep out of the reach and sight of children.

Do not use this medicine after the expiry date (EXP) shown on the carton or label. The expiry date refers to the last day of the month. Store below 25°C. Do not refrigerate. Store in the original container in order to protect from light. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. Further information

## Ingredients

Each 5ml of Paralink Six Plus contains 250mg of the active ingredient paracetamol. The other ingredients are sorbitol (E420), liquid maltitol (E965), propylene glycol, macrogol 4000, glycerol, potassium sorbate, ethyl parahydroxybenzoate (E214), methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), citric acid, neohesperidin-dihydrochalcone, saccharin sodium, strawberry flavour and purified water.

## What the medicine looks like

Paralink Six Plus is a colourless/straw coloured, sugar free oral solution with a strawberry odour and taste. This medicine is available in pack sizes of 60ml and 70ml. Not all pack sizes may be available.

## **Product Authorisation Holder**

Phoenix Healthcare Limited Suite 12, Bunkilla Plaza, Bracetown Business Park, Clonee, County Meath, Ireland

### Manufacturer

Ricesteele Manufacturing Limited Tallaght, Dublin 24, Ireland

### **Product authorisation number**

PA 1721/006/004

Date of leaflet revision: May 2022

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