Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Paralink Paracetamol Oral Solution 120 mg/5 ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains Paracetamol 120mg.

Each 5ml also contains:
Sorbitol 70% (E420) 1.5 g
Propylene Glycol 0.5 g
Liquid Maltitol 0.3 g
Nipasept 5.0 mg
Nipasept contains a mixture of methyl, ethyl and propyl parahydroxybenzoate (E218, E216, E214).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral Solution.
Colourless liquid with strawberry odour and taste.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Paralink Paracetamol Solution is indicated as an analgesic and antipyretic. It is used in the treatment of mild to moderate pain, for the relief of symptoms of colds and influenza and to reduce fever, including post-vaccination fever in childhood.

4.2 Posology and method of administration

Age	Dose
For post-vaccination fever for babies aged between 2 – 3 months	2.5mL If necessary, after 4 – 6 hours, give a second 2.5mL dose.
o Do not give to babies less than 2 months of age o Do not give more than 2 doses o Leave at least 4 hours between doses o If further doses are needed, talk to your doctor or pharmacist	

Child's Age	How Much	How often (in 24 hours)
3 – 6 months	2.5mL	4 times
6 – 24 months	5mL	4 times
2 – 4 years	7.5mL	4 times
4 – 6 years	10mL	4 times
o Do not give more than 4 doses in any 24 hour period o Leave at least 4 hours between doses o Do not give this medicine to your child for more than 3 days without speaking to your doctor or pharmacist		

4.3 Contraindications

Patients with rare hereditary problems of fructose intolerance should not take this medicine.
Hypersensitivity to paracetamol or to any of the other constituents.

4.4 Special warnings and precautions for use

Never give more medicine than shown in the table.
Always use the syringe supplied with the pack.
Do not give to babies less than 2 months of age.
For infants 2-3 months no more than two doses should be given.
Do not give more than 4 doses in any 24 hour period.
Leave at least 4 hours between doses.
Prolonged use without medical supervision can be harmful.
Do not give this medicine to your child for more than 3 days without speaking to your doctor or pharmacist. If symptoms persist consult your doctor.
Do not give with any other paracetamol containing products.
The product should be administered with caution to patients with known liver or renal impairment.
Immediate medical advice should be sought in the event of an overdose, because of the risk of irreversible liver damage. As with all medicines, if your child is currently taking any medicine consult your doctor or pharmacist before taking this product.
Keep out of the reach and sight of children.
Caution is advised if paracetamol is administered concomitantly with flucloxacillin due to increased risk of high anion gap metabolic acidosis (HAGMA), particularly in patients with severe renal impairment, sepsis, malnutrition, and other sources of glutathione deficiency (e.g., chronic alcoholism), as well as those using maximum daily doses of paracetamol. Close monitoring, including measurement of urinary 5-oxoproline, is recommended.

4.5 Interaction with other medicinal products and other forms of interactions

The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular use of paracetamol with increased bleeding; occasional doses have no significant effect.
The rate of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by choleystyramine.

Chronic alcohol intake can increase the hepatotoxicity of paracetamol overdose. Acute alcohol intake may diminish an individual's ability to metabolise large doses of paracetamol, the plasma half-life of which can be prolonged.
The use of drugs that induce hepatic micosomal enzymes, such as anticonvulsants and oral contraceptives, may increase the extent of metabolism of paracetamol, resulting in reduced plasma concentrations of the drug and a faster elimination rate.
Caution should be taken when paracetamol is used concomitantly with flucloxacillin as concurrent intake has been associated with high anion gap metabolic acidosis, especially in patients with risks factors (see section 4.4).

4.6 Fertility, pregnancy and lactation

Pregnancy
A large amount of data on pregnant women indicate neither malformative, nor feto/neonatal toxicity. Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusive results. If clinically needed, paracetamol can be used during pregnancy however it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency.

Lactation
Paracetamol is excreted in breast milk but not in a clinically significant amount. Available published data does not contraindicate breast feeding.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Adverse effects of paracetamol are rare but hypersensitivity including skin rash may occur. Very rare cases of serious skin reactions have been reported. There have been a few reports of blood dyscrasias including thrombocytopenia and agranulocytosis.

Chronic hepatic necrosis has been reported in a patient who took daily therapeutic doses of paracetamol for about a year and liver damage has been reported after daily ingestion of excessive amounts for shorter periods.

A review of a group of patients with chronic active hepatitis failed to reveal differences in the abnormalities of liver function in those who were long-term users of paracetamol nor was the control of the disease improved after paracetamol withdrawal.

Nephrotoxic effects following therapeutic doses of paracetamol are uncommon. Papillary necrosis has been reported after prolonged administration.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions 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.

4.9 Overdose

Liver damage is possible in adults who have taken 10g or more of paracetamol. Ingestion of 5g or more of paracetamol may lead to liver damage if the patient has risk factors, including the following ones:

Risk factors
a) Long term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St John's Wort or other drugs that induce liver enzymes, or
b) regular consumption of ethanol in excess of recommended amounts, or
c) likely glutathione depletion, e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia.
Symptoms
Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, haemorrhage, hypoglycaemia, cerebral oedema and death. Acute renal failure with acute tubular necrosis, strongly suggested by loin pain, haematuria, and proteinuria, may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.

Treatment
Immediate treatment is essential in the management of paracetamol overdose. Despite a lack of significant early symptoms, patients should be referred to hospital urgently for immediate medical attention. Symptoms may be limited to nausea or vomiting and may not reflect the severity of overdose or the risk of organ damage. Management should be in accordance with established treatment guidelines.

Treatment with activated charcoal should be considered if the overdose has been taken within 1 hour. Plasma paracetamol concentration should be measured at 4 hours or later after ingestion (earlier concentrations are unreliable). Treatment with N-acetylcysteine may be used up to 24 hours after ingestion of paracetamol, however, the maximum protective effect is obtained up to 8 hours' post-ingestion. The effectiveness of the antidote declines sharply after this time. If required the patient should be given intravenous N-acetylcysteine, in line with the established dosage schedule. If vomiting is not a problem, oral

methionine may be a suitable alternative for remote areas, outside hospital. Management of patients who present with serious hepatic dysfunction beyond 24h from ingestion should be discussed with a liver unit.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Analgesic, Antipyretic; N02 BE01.
Paracetamol is an antipyretic and analgesic proven in paediatric use. Paracetamol produces antipyresis through action on the hypothalamic heat-regulation centre and analgesia by elevation of the pain threshold. Paracetamol has analgesic and antipyretic actions similar to those of aspirin but it has no useful anti-inflammatory properties.

5.2 Pharmacokinetic properties

Paracetamol has analgesic and antipyretic actions but only weak anti-inflammatory properties.

Paracetamol is rapidly and almost completely absorbed from the gastrointestinal tract. Peak plasma concentrations occur within 30 to 60 minutes, with slightly faster absorption of liquid preparations. Usual analgesic doses produce total serum concentrations of 5 to 20micrograms/ml. A good correlation between serum concentration and analgesic effect has not been found.

Paracetamol is distributed into most body tissues, it crosses the placenta and it is present in breast milk. Serum protein binding varies from 20% to 50% at toxic serum concentrations.

Paracetamol is metabolised predominantly in the liver and excreted in the urine mainly as glucuronide and sulfate conjugates. Less than 5% is excreted as unchanged paracetamol. The elimination half-life varies from about 1 to 3 hours and is prolonged in neonates and in patients with hepatic impairment.

Total body clearance of paracetamol is reduced in neonates and increases with age.

5.3 Preclinical safety data

Conventional studies using the currently accepted standards for the evaluation of toxicity to reproduction and development are not available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene Glycol
Macrogol 4000
Glycerol
Sorbitol 70% (Non-crystallising) (E420)
Liquid Maltitol (E965)
Potassium Sorbate
Citric Acid
Neohesperidin Dihydrochalcone
Saccharin Sodium
Nipasept
Strawberry flavour 221047
Purified Water

Nipasept contains a mixture of the methyl, ethyl and propyl esters of hydroxybenzoic acid. (E218,E216, E214).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store below 25°C. Keep in the original container. Do not refrigerate. Protect from light.

6.5 Nature and contents of container

Amber hydrolytic resistance Type III Soda-lime-silica glass bottles with child resistant tamper evident closure. The closure is manufactured from polypropylene with a polyethylene liner and tamper evident band. A 5ml dosing syringe with markings at 2.5ml and 5ml is provided with the bottle. Pack sizes 100ml and 60ml.Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Phoenix Healthcare Ltd
Suite 12 Bunkilla Plaza
Bracetown Business Park
Clonee
Co Meath
Ireland

8 MARKETING AUTHORISATION NUMBER

PA1721/006/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 March 1984
Date of last renewal: 01 March 2009

10 DATE OF REVISION OF THE TEXT

June 2022