SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

LOTEMP® PARACETAMOL SUSPENSION

Strength

Each 5ml contains:

Paracetamol BP…… 125mg

Pharmaceutical/ Dosage form

Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains:

Paracetamol BP…… 125mg

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension

Pink coloured, viscous aqueous suspension

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of mild to moderate pain, including headache, migraine, neuralgia, toothache, sore throat, period pains, aches and pains.

For the reduction of fever and to be used as an adjunctive treatment to relieve symptoms of cold and flu.

4.2 Posology and method of administration

Posology

For the relief of fever after vaccinations at 2, 3 and 4 months One 2.5 mL. This dose may be given up to 4 times a day starting at the time of vaccination. Do not give more than 4 doses in any 24-hour period. Leave at least 4 hours between doses. If your baby still needs this medicine two days after receiving the vaccine talk to your doctor or pharmacist.		
Age: 2 – 3 months	**Dose**	
Pain and other causes of fever - if your baby weighs over 4 kg and was born after 37 weeks	One 2.5 mL If necessary, after 4-6 hours, give a second 2.5 mL dose	
• Do not give to babies less than 2 months of age • Leave at least 4 hours between doses • Do not give more than 2 doses. This is to ensure that fever that may be due to a serious infection is quickly diagnosed. If your child is still feverish after two doses, talk to your doctor or pharmacist.		
Child's Age	**How Much**	**How often (in 24 hours)**
3 – 6 months	2.5 mL	4 times
6 – 24 months	5 mL	4 times
2 – 4 years	7.5 mL	4 times
4 – 8 years	10 mL	4 times
8 – 10 years	15 mL	4 times
10 - 12 years	20 mL	4 times
• Do not give more than 4 doses in any 24-hour period • Leave at least 4 hours between doses • Do not give this medicine to your child for more than 3 days without speaking to your doctor or pharmacist		

Method of administration

For oral administration only

It is important to shake the bottle well before use

4.3 Contraindications

Hypersensitivity to paracetamol or to any of the excipients listed in section 6.1.

Patients with severe hepatic dysfunction.

4.4 Special warnings and precautions for use

Care is advised in the administration of paracetamol to patients with severe renal or severe hepatic impairment. The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease.

• Do not give with any other paracetamol-containing products.

• For oral use only.

• Do not give to babies less than 2 months of age.

• For infants 2-3 months not more than 2 doses should be given.

• Do not give more than 4 doses in any 24-hour period.

• Leave at least 4 hours between doses.

• Do not give this medicine to your child for more than 3 days without speaking to your doctor or pharmacist.

• As with all medicines, if your child is currently taking any medicine consult your doctor or pharmacist before taking this product.

• Do not store above 30°C. Protect from light. Store in the original package.

• Immediate medical advice should be sought in the event of an overdose, even if the child seems well, because of the risk of delayed serious liver damage.

• If symptoms persist, consult your doctor.

• Keep out of the reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

The hepatotoxicity of Paracetamol, particularly after overdosage, may be increased by drugs which induce liver microsomal enzymes such as barbiturates, tricyclic antidepressants, and alcohol.

Chronic alcohol intake can increase the hepatotoxicity of paracetamol overdose and may have contributed to the acute pancreatitis reported in one patient who had taken an overdose of paracetamol. 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 speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by colestyramine.

The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.

Antivirals: Regular use of Paracetamol possibly reduces metabolism of Zidovudine (increased risk of neutropenia).

The use of drugs that induce hepatic microsomal 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.

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.

Breast-feeding

Paracetamol is excreted in breast milk but not in clinically significant quantities. Available published data do not contraindicate breast feeding.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Adverse effects of paracetamol are rare but hypersensitivity including skin rash may occur. There have been reports of blood dyscrasias including thrombocytopenia and agranulocytosis, but these were not necessarily causality related to paracetamol.

Very rare cases of serious skin reactions have been reported.

Cases of acute pancreatitis have been reported. Paracetamol has been widely used and reports of adverse reactions are rare and are generally associated with overdosage.

Allergic reactions occur occasionally.

Nephrotoxic effects are uncommon and have not been reported in association with therapeutic doses, except after prolonged administration.

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 (see below).

Risk factors:

If the patient

a) Is on long term treatment with carbamazepine, phenobarbital, phenytoin, primidone, rifampicin, St John's Wort or other drugs that induce liver enzymes.

Or

b) Regularly consumes ethanol in excess of recommended amounts

Or

c) Is likely to be glutathione depleted 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.

Management:

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, see BNF overdose section.

Treatment with activated charcoal should be considered if the overdose has been taken within 1 hour. Plasma paracetamol concentration should be measured 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 hospitals. Management of patients who are present with serious hepatic dysfunction beyond 24h from ingestion should be discussed with the NPIS or a liver unit.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The mechanism of analgesic action has not been fully determined. Paracetamol may act predominantly by inhibiting prostaglandin synthesis in the central nervous system (CNS) and, to a lesser extent, through a peripheral action by blocking pain impulse generation. The peripheral action may also be due to the inhibition of prostaglandin synthesis or to inhibition of the synthesis or actions of other substances that sensitise pain receptors to mechanical or chemical stimulation.

Paracetamol probably produces antipyresis by acting centrally on the hypothalamic heat regulating centre to produce peripheral vaso-dilation resulting in increased blood flow through the skin, sweating and heat loss. The central action probably involves inhibition of prostaglandin synthesis in the hypothalamus.

5.2 Pharmacokinetic properties

Absorption

Paracetamol is readily absorbed from the gastrointestinal tract.

Distribution

Peak plasma concentrations occur about 30 minutes to 2 hours after oral doses. Paracetamol is distributed into most body tissues. It crosses the placenta and is present in breast milk. Plasma-protein binding is negligible at usual therapeutic concentrations but increases with increasing concentrations.

Biotransformation

It is metabolised in the liver. A minor hydroxylated metabolite which is usually produced in very small amounts by mixed-function oxidases in the liver and which is usually detoxified by conjugation with liver glutathione may accumulate following Paracetamol overdosage and cause liver damage.

Elimination

It is excreted in the urine, mainly as the glucuronide and sulfate conjugates. The elimination half-life varies from about 1 to 4 hours.

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

S.NO	Composition	Reference
1.	Sucrose	BP
2.	Liquid Sorbitol (non-crystalizing)	BP
3.	Methyl Paraben	BP
4.	Propyl Paraben	BP
5.	Polysorbate 80	BP
6.	Xanthan Gum	BP
7.	Colloidal Silicon dioxide	BP
8.	Cochineal Red colour	BP
9.	Aromas Raspberry	IHS
10.	Purified Water	BP

6.2 Incompatibilities

None known

6.3 Shelf life

3 Years

6.4 Special precautions for storage

Store below 30°C. Protect from light. Store in the original package.

6.5 Nature and contents of container

Bottles:	Amber PET bottle
Closure:	Aluminum ROPP cap
Pack size:	60ml
Dosing device:	2.5/5ml polypropylene measuring cup

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. APPLICANT/HOLDER OF CERTIFICATE PRODUCT REGISTRATION.

Unique Pharmaceuticals Limited
11, Fatai Atere Way, Matori-Mushin Lagos
Tel: +234 8097421000
Email: mail@uniquepharm.com

8. DRUG PRODUCT MANUFACTURER

Unique Pharmaceuticals Limited
Km 38, Abeokuta Road, Sango-Ota,
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9. NAFDAC REGISTRATION NUMBER(S)

04-4988

10. DATE OF REVISION OF THE TEXT

26/08/2026