SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

LOTEMP® TABLETS

Strength

Each tablet contains 500mg Paracetamol BP.

Pharmaceutical/Dosage form

Tablet

White circular uncoated tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 500mg Paracetamol BP.

Excipients:

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Tablet

White circular tablet debossed with “LOTEMP” and P500 on one side and “UNIQUE” on the other side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Lotemp has analgesic and antipyretic actions similar to those of aspirin and hence is a suitable alternative for patients sensitive to aspirin.

For the relief of mild to moderate pain and febrile conditions, *e.g.* headache, toothache, colds, influenza, rheumatic pain and dysmenorrhea.

4.2 Posology and method of administration

Posology

Adults including the elderly and children over 16 years: One to two tablets every 4-6 hours as required, to a maximum of 8 tablets daily in divided doses.

Children 10-15 years: One tablet every 4-6 hours as necessary to a maximum of 4 doses in 24 hours.

Children under 10 years: Not recommended for children under 10 years of age. Alternative presentations of paracetamol are recommended for paediatric usage in order to obtain suitable doses of less than 500mg.

Method of Administration

For oral administration.

4.3 Contraindications

• Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Where analgesics are used long-term (>3 months) with administration every two days or more frequently, headache may develop or worsen. Headache induced by overuse of analgesics should not be treated by dose increase. In such cases, the use of analgesics should be discontinued in consultation with the doctor.

Care is advised in the administration of lotemp to patients with alcohol dependency (see section 4.9), severe renal or severe hepatic impairment. The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease.

Do not exceed the recommended dose.

If symptoms persist consult your doctor.

Keep out of the reach and sight of children.

Do not take with any other paracetamol-containing products.

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

4.5 Interaction with other medicinal products and other forms of interaction

- Anticoagulants - the effect of warfarin and other coumarins may be enhanced by prolonged regular use of lotemp with increased risk of bleeding. Occasional doses have no significant effect.
- Metoclopramide – may increase speed of absorption of lotemp.
- Domperidone – may increase speed of absorption of lotemp.
- Colestyramine – may reduce absorption if given within one hour of lotemp.

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 lotemp in utero show inconclusive results. If clinically needed, lotemp 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

Lotemp is excreted in breast milk but not in a clinically significant amount. 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, neutropenia, pancytopenia, leukopenia and agranulocytosis but these were not necessarily causality related to Lotemp

Very rare cases of serious skin reactions have been reported.

4.9 Overdose

Liver damage is possible in adults who have taken 10g or more of Lotemp. Ingestion of 5g or more of

Lotemp may lead to liver damage if the patient has risk factors (see below).

Risk Factors:

If the patient

a) Is long term treatment with carbamazepine, phenobarbital,

phenytoin, primidone, rifampicin, St John's Wort or other drugs than induce liver enzymes.

Or

b), regularly consumes ethanol in excess of the recommended amounts.

Or

c), Is likely to be glutathione depleted e.g. eating disorders, cystic fibrosis, HIV, starvation, cachexia.

Symptoms

Symptoms of Paracetamol overdose 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 poisioning, 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 energy 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 lotemp 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

Pharmacotherapeutic group: Other analgesics and antipyretics, Anilides

Lotemp has analgesic and antipyretic properties, but it has no useful anti-inflammatory properties.

Lotemp's effects are thought to be related to inhibition of prostaglandin synthesis

Mechanisms of action/Effect

Analgesic- the mechanism of analgesic action has not been fully determined. Paracetamol may act predominantly

by inhibiting prostaglandin synthesis in the central nervous system and to a lesser extent, through peripheral action

by blocking pain-impulse generation.

The peripheral action may also be due to inhibition of prostaglandin synthesis or to the synthesis or actions of

other substances that sensitize pain receptors to mechanical or chemical stimulation.

Antipyretic- paracetamol probably produces antipyresis by acting centrally on the hypothalamic heat-regulation centre

to produce peripheral vasodilation 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

Lotemp is readily absorbed from the gastrointestinal tract.

Distribution

Peak plasma concentrations occur about 30 minutes to 2 hours after oral doses. Lotemp 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 of 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.	Maize Starch (Paste)	BP
2.	Maize Starch (Internal)	BP
3.	Methyl Paraben	BP
4.	Propyl Paraben	BP
5.	TALC Powder	BP
6.	Magnesium Stearate	BP
7.	Microcrystalline Cellulose	BP

6.2 Incompatibilities

None known.

6.3 Shelf life
3 years

6.4 Special precautions for storage

Store below 30°C in a dry place. Keep out the reach of children.

6.5 Nature and contents of container

a. Blisters consisting of hard tempered aluminum foil, compatible with PVC or PVDC, Thermo-sealed.

12 tablets per blister and 8 blisters per cardboard box.

b. Low density polyethylene jars with lid containing 1000 tablets in sealed polyethylene bags.

6.6 Special precautions for disposal and other handling

Not applicable.

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

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9. NAFDAC REGISTRATION NUMBER(S)

04-7111

10. DATE OF REVISION OF THE TEXT

06/05/2026