Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:
Paracetamol 500mg Tablets

2. Qualitative and quantitative composition
Each tablet contains 500 mg paracetamol

3. Pharmaceutical form
Tablet

White to off white round flat beveled edge uncoated tablets having breakline on one side & plain on another side

For a full list of excipients, see section 6.1.

4. Clinical particulars
4.1 Therapeutic indications
For the relief of headache, rheumatic pains, neuralgia and relief of symptoms of colds and influenza.

4.2 Posology and method of administration
For oral use.

Adults and children over 16 years of age

One to two tablets every 4-6 hours when necessary to a maximum of 4 doses in 24 hours.

Children 12 to 15 years of age

One tablet every 4-6 hours when necessary to a maximum of 4 doses in 24 hours.

Elderly

There is no need for dosage reduction in the elderly.

4.3 Contraindications
Hypersensitivity to paracetamol and/or any of the other ingredients. Severe liver disease.

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.

Cases of high anion gap metabolic acidosis (HAGMA) due to pyroglutamic acidosis have been reported in patients with severe illness such as severe renal impairment and sepsis, or in patients with malnutrition or other sources of glutathione deficiency (e.g. chronic alcoholism) who were treated with paracetamol at therapeutic dose for a prolonged period or a combination of paracetamol and flucloxacillin. If HAGMA due to pyroglutamic acidosis is suspected, prompt discontinuation of paracetamol and close monitoring is recommended. The measurement of urinary 5-oxoproline may be useful to identify pyroglutamic acidosis as underlying cause of HAGMA in patients with multiple risk factors.

Do not exceed the stated dose.

Not to be given to children under 12 years, without medical advice.

Dosage should not be continued for more than three days without consulting your doctor.

If symptoms persist, consult your doctor.

Do not take with any other paracetamol-containing products.

Keep all medicines out of the reach and sight of children.

Label:

Immediate medical advice should be sought in the event of an overdose, even if you feel well.

Leaflet or combined label/leaflet:

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

The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by cholestyramine.

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.

Caution should be taken when paracetamol is used concomitantly with flucloxacillin as concurrent intake has been associated with high anion gap metabolic acidosis due to pyroglutamic acidosis, especially in patients with risks factors (see section 4.4)

4.6 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 do not contraindicate breast feeding.

4.7 Effects on ability to drive and use machines

Paracetamol 500mg Tablets has no known influence on the ability to drive and use machines.

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. Very rarely there have been reports of blood dyscrasias including thrombocytopenia and agranulocytosis, but these were not necessarily causality related to paracetamol.

Metabolism and nutrition disorders

High anion gap metabolic acidosis with frequency “Not known” (cannot be estimated from the available data)

Description of selected adverse reactions

High anion gap metabolic acidosis

Cases of high anion gap metabolic acidosis due to pyroglutamic acidosis have been observed in patients with risk factors using paracetamol (see section 4.4). Pyroglutamic acidosis may occur as a consequence of low glutathione levels in these patients.

Reporting of suspected adverse reactions

Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

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, phenobarbitone, 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 deplete 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 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 24 h 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

ATC Code - N02BE01

Paracetamol is a peripherally acting analgesic with antipyretic activity.

5.2 Pharmacokinetic properties

Paracetamol is readily absorbed from the gastrointestinal tract with peak plasma concentrations occurring about 30 minutes to 2 hours after ingestion. Paracetamol is metabolised in the liver and excreted in the urine mainly as the glucoronide and sulphate conjugates, with about 10% as glutathione conjugates. Less than 5% is excreted as unchanged paracetamol. The elimination half-life varies from about 1-4 hours. Plasma protein binding is negligible at usual therapeutic concentrations, although this is dose-dependent.

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

Maize starch,Gelatin, Magnesium stearate ,Colloidal anhydrous Silica,Sodium starch glycollate (Type A),Purified Talcum

6.2 Incompatibilities

Not applicable.

6.3 Shelf-Life

36 months

6.4 Special Precautions for storage

None - This medicinal product does not require any special storage conditions.

6.5 Nature and Content of container

Child-resistant blisters of 250µm PVC/ 40gsm PVdC/ 35gsm Glassine Paper/ 9µm Soft Temper Aluminium foil**.** Pack sizes of 6, 8, 10, 12, 16, 18, 20, 24, 25, 30, 32 tablets (not all pack sizes will be marketed).

Child-resistant blisters of 250µm PVC/ 35gsm Glassine Paper/ 9µm Soft Temper Aluminium foil. Pack sizes of 6, 8, 10, 12, 16, 18, 20, 24, 25, 30, 32 tablets (not all pack sizes will be marketed).

Child-resistant blisters of 250µm PVC / 40gsm PVdC. Lidding foil: 20 micron hard aluminium foil / 15 micron PVC. Pack sizes of 6, 8, 10, 12, 16, 18, 20, 24, 25, 30, 32 tablets (not all pack sizes will be marketed).

6.6 Special precautions for disposal and other handling
No special requirements.

7. Marketing Authorization Holder
Victoria Healthcare Limited

8. Marketing Authorization Number
H2025/CTD11659/25789

9. Date of first authorization/renewal of the authorization
2025 May 26

10. Date of revision of the text
2025 May 26