Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:

Gacet 500 (Paracetamol 500 mg Effervescent tablets)
Gacet 1000 (Paracetamol 1000 mg Effervescent tablets)

2. Qualitative and quantitative composition

Gacet 500 effervescent tablet contains paracetamol 500mg
Gacet 1000 effervescent tablet contains paracetamol 1000mg

For a full list of excipients, see section 6.1

3. Pharmaceutical form

Effervescent tablets.
White to off white colour, round shape, flat-faced bevelled edge tablet, plain on both sides.

4. Clinical particulars

4.1 Therapeutic indications

Paracetamol is a mild analgesic and antipyretic indicated for relief of mild to moderate pain, including headache, migraine, neuralgia, toothache, period pain, and pain caused by rheumatism. It is also used to relieve the symptoms of colds and flu, and sore throats.

4.2 Posology and method of administration

Adults and children over 15 years:
1000 mg taken orally every 4-6 hours if necessary. Do not exceed 4000mg in 24 hours.
Children 12 to 15 years:
500 mg taken orally every 4-6 hours when necessary to a maximum of 2000 mg in 24 hours.
Children under 12 years:
Not to be given to children under 12 years.
Elderly patients:
Normal adult dose unless there is impaired kidney or liver function.

Directions: The tablets must be dissolved in a glass of water. The tablets dissolve more quickly in warm water if stirred.

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

Care is advised in the administration of paracetamol to patients with severe renal or severe hepatic impairment and in those with non-cirrhotic

alcoholic liver disease. The hazards of overdose are greater in those with alcohol liver disease.
Do not take more medicine than the label tells you to. Do not take for more than 3 days without consulting a doctor. If you do not get better, talk to your doctor.
Contains Paracetamol. Do not take anything else containing paracetamol while taking this medicine.
Talk to your doctor at once if you take too much of this medicine, even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage. Patients should be advised that paracetamol may cause severe skin reactions. If a skin reaction such as skin reddening, blisters, or rash occurs, they should stop use and seek medical assistance right away.
Each tablet contains sodium. This sodium should be taken into account when prescribing for patients on a sodium-restricted diet.

4.5 Interaction with other medicinal products and other forms of interaction

Cholestyramine: The speed of absorption of paracetamol is reduced by cholestyramine. Therefore, the cholestyramine should not be taken within one hour if maximal analgesia is required.
Metoclopramide and Domperidone: The absorption of paracetamol is increased by metoclopramide and domperidone. However, concurrent use need not be avoided.
Warfarin: 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.
Chloramphenicol: Increased plasma concentration of chloramphenicol.

4.6 Pregnancy and Lactation

Pregnancy

A large amount of data on pregnant women indicates 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. Breastfeeding 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

None known.

4.8 Undesirable effects

Adverse effects of Paracetamol are rare. Very rare cases of serious skin reactions have been reported. There have been reports of blood dyscrasias

including thrombocytopenia purpura, methaemoglobenaemia and agranulocytosis, but these were not necessarily causally related to Paracetamol.

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 pharmacy and poison 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

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 Nacetylcysteine may be used up to 24 hours after ingestion of paracetamol however, the maximum protective effect is obtained up to 8

hours post ingestion. 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 hours from ingestion should be discussed with the NPIS or a liver unit.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Analides, Other Analgesics and Antipyretics.
ATC Code: N02B E01

Mechanism of action

Analgesic – 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 inhibition of prostaglandin synthesis or to inhibition of the synthesis or actions of other substances that sensitise 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 and Fate

Paracetamol is readily absorbed from the gastrointestinal tract with peak plasma concentrations occurring 30 minutes to 2 hours after ingestion. It is metabolised in the liver and excreted in the urine mainly as the glucuronide and sulfate conjugates. Less than 5% is excreted as unchanged paracetamol. The elimination half-life varies from about 1 to 4 hours. Plasma-protein binding is negligible at usual therapeutic concentrations but increases with increasing concentrations. 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.

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

Anhydrous Citric acid, Sodium Bicarbonate, Sodium Sacchrarin, Sodium Carbonate, Povidone(K30), Simethicone, Polysorbate 80, Isopropyl Alcohol, Purified water, Aspartame, Sodium Benzoate, Powdarome Orange 4153

6.2 Incompatibilities

Not applicable.

6.3 Shelf-Life

2 years.

6.4 Special Precautions for storage

Store below 30°C. Protect from light and moisture.

6.5 Nature and Content of container

4 x 4 Aluminium strips are packed in carton along with insert.

6.6 Special precautions for disposal and other handling

Not applicable.

7. Marketing Authorization Holder

Bliss GVS Pharma Limited.

8. Marketing Authorization Number

Gacet 500 - CTD8367
Gacet 1000 – CTD11321

9. Date of first authorization/renewal of the authorization

Gacet 500 – 08/11/2023
Gacet 1000 – 30/05/2024

10. Date of revision of the text

05/05/2025