Summary Product Characteristics for Pharmaceutical Product

1. Name of the medicinal product

Perfamol 500mg
Perfamol 1000mg

2. Qualitative and quantitative composition

Each tablet contains Paracetamol 500.0 mg

Each tablet contains Paracetamol 1000.0 mg

Excipients with known effect

Contains sodium and sorbitol

For a full list of excipients, see section 6.1

3. Pharmaceutical form

Effervescent tablets.
Soluble tablets are white to off-white coloured circular flat-bevelled tablets plain on both sides.

4. Clinical particulars

4.1 Therapeutic indications

Paracetamol is a mild analgesic and antipyretic and is recommended for the treatment of most painful and febrile conditions, for example, headaches including migraine and tension headaches, toothache, backache, rheumatic and muscle pains, dysmenorrhoea, sore throat, and for relieving the fever, aches and pains of colds and flu.

4.2 Posology and method of administration

Perfamol 500mg

Adults, the elderly, and children aged 16 years and over:

1 -2 tablets in at least half a tumbler of water, up to 4 times daily as required.

Children:

Aged 10-15 years: 1 tablet dissolved in water up to 4 times daily.
Not recommended for children under the age of 10 years.
Children should not be given paracetamol for more than 3 days without consulting a doctor.

Doses of paracetamol should not be given more frequently than every 4 hours, and not more than 4 doses should be given in any 24-hour period.

Oral administration only.

Perfamol 1000 mg

Use in adults and adolescents over 50kg of body weight and aged 16 years and above.
Adults and adolescents > 50 kg of body weight:
Take one tablet every four, six or eight hours up to a maximum of 4 tablets in 24 hours or 4000 mg in 24 hours.
Maximum daily dose:
• The maximum daily dose of Paracetamol must not exceed 4000 mg.
• Maximum single dose is 1000 mg (1 soluble tablet).

4.3 Contraindications

Hypersensitivity to paracetamol or any of the other constituents.

4.4 Special warnings and precautions for use

Contains paracetamol. Do not use with any other paracetamol-containing products.
Underlying liver disease increases the risk of paracetamol-related liver damage. Patients who have been diagnosed with liver or kidney impairment must seek medical advice before taking this medication.
Do not exceed the stated dose.
Patients should be advised to consult their doctor if their headaches become persistent.
Patients should be advised to consult a doctor if they suffer from non-serious arthritis and need to take painkillers every day.
The paracetamol effervescent tablet is considered high in sodium. To be taken into consideration by patients on a controlled sodium diet.
The medicinal product contains sorbitol. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

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

4.6 Pregnancy and lactation

Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusive results. If clinically needed, paracetamol can be used during pregnancy if clinically needed, however, as with any medicine it should be used at the lowest effective dose for the shortest possible time.

Paracetamol is excreted in breast milk but not in a clinically significant amount in recommended dosages. Available published data do not contraindicate breastfeeding.

4.7 Effects on the ability to drive and use machines

None

4.8 Undesirable effects

Adverse events of paracetamol from historical clinical trial data are both infrequent and from small patient exposure. Accordingly, events reported from extensive post-marketing experience at therapeutic/labelled dose and considered attributable are tabulated below by system class and frequency.

The following convention has been utilised for the classification of the undesirable effects: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1000 to <1/100), rare (≥1/10,000 to <1/1000) and very rare (<1/10,000), not known (cannot be estimated from available data).

Adverse event frequencies have been estimated from spontaneous reports received through post-marketing data.

Body System	**Undesirable effect**	**Frequecny**
Blood and lymphatic system disorders	Thrombocytopenia Agranulocytosis	Very rare
Immune system disorders	Anaphylaxis Cutaneous hypersensitivity reactions including, among others, skin rashes and angiodema. Very rare cases of serious skin reactions have been reported	Very rare
Respiratory, thoracic and mediastinal disorders	Bronchospasm	Very rare
Hepatobiliary disorders	Hepatic dysfunction	Very rare

There have been cases of bronchospasm with paracetamol, but these are more likely in asthmatics sensitive to aspirin or other NSAIDs.

Reporting of suspected adverse reactions:
Healthcare professionals are asked to report any suspected adverse reactions via the 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 10 g or more of paracetamol. Ingestion of 5 g or more of paracetamol may lead to liver damage if the patient has risk factors (see below).

Risk Factors:
If the patient
• Is on long-term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St John's Wort or other drugs that induce liver enzymes.
Or
• Regularly consumes ethanol in excess of recommended amounts.
Or
• Is likely to be glutathione depleted e.g. eating disorders, cystic fibrosis, HIV infection, 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 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 the 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- 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 the 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.
High doses of sodium bicarbonate may be expected to induce gastrointestinal symptoms including belching and nausea. In addition, high doses of sodium

bicarbonate may cause hypernatraemia; electrolytes should be monitored and patients managed accordingly.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Paracetamol is a well established analgesic

5.2 Pharmacokinetic properties

Paracetamol is rapidly and almost completely absorbed from the gastrointestinal tract. The concentration of the drug in plasma reaches a peak in 30 - 60 minutes and the plasma half-life is 1 - 4 hours.
Paracetamol is relatively uniformly distributed throughout most body fluids and exhibits variable protein binding. Excretion is almost exclusively renal in the form of conjugated metabolites.

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

Povidone K-30

Saccharin Sodium

Purified Water

Anhydrous Sodium Carbonate

Simethicone Emulsion 100%

Polysorbate 80

Aspartame

Dry Strawberry Flavour

6.2 Incompatibilities

None.

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store below 30°C

6.5 Nature and contents of the container

Perfamol 500 mg
Alu-Alu blister pack
Pack size: 4x4

Perfamol 1000mg
Alu-Alu blister pack
Pack size: 1x4 tablets

6.6 Special precautions for disposal and other handling

None

7. Marketing authorisation holder and manufacturing site addresses

Signature Healthcare Ltd.
Cape Business Park, Along Thika Super Highway
P.O. Box 66172-00800, Nairobi.
KENYA
Mobile: +254-705617118
E-Mail:info@signaturehealthcareltd.com, mohamediftikharsaeed@gmail.com, info@signaturehealthcareltd.co.ke

Manufacturing site address:

Coral Laboratories Limited
Plot No.27-28, Pharmacity, Selaqui,
Dehradun, Uttarakhand INDIA.
Phone: 91-0135-2698 422, 2698 466
Email: doon@corallab.com; exports@corallab.com

8. Marketing authorisation number(s)

CTD9686- Perfamol 500 mg

CTD9685- Perfamol 1000mg

9. Date of first authorisation/renewal of the authorisation

Date of first authorization: 09-August-2023

10. Date of revision of the text

14-Sep-2023

11. Dosimetry:

Not Applicable

12. Instructions for preparation of radiopharmaceuticals:

Not Applicable