Summary Product Characteristics for Pharmaceutical Product

1. Name of the medicinal product

Ferodol 1000mg

2. Qualitative and quantitative composition

Each tablet contains Paracetamol 1000mg

Excipients with known effect

Contains Sodium Benzoate and Sodium Bicarbonate.

For a full list of excipients, see section 6.1

3. Pharmaceutical form

Effervescent tablets.

White to off-white colour, round flat faced bevelled edge tablets

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

This tablet is reserved for use in adults and adolescents aged 16 years and above.

Maximum daily dose:
• The maximum daily dose of Paracetamol must not exceed 4000 mg.
• Maximum single dose is 1000 mg (1 effervescent tablet).
Paracetamol 1000 mg Effervescent Tablets are for oral administration. The tablets should be placed in a full tumbler of water immediately before use and allowed to dissolve completely before swallowing.

Frequency of administration:
Doses of Paracetamol 1000 mg Effervescent Tablets should not be given more frequently than every 6 hours, and not more than 4 doses should be given in any 24-hour period.

Method of administration:

For oral use.

4.3 Contraindications

Hypersensitivity to paracetamol or any of the other constituents.

4.4 Special warnings and precautions for use

Prolonged or frequent use is discouraged. Patients should be advised not to take other Paracetamol-containing products concurrently. Taking multiple daily doses in one administration can severely damage the liver. Prolonged use except under medical supervision may be harmful. In children treated with 60mg/kg daily of Paracetamol, the combination with another antipyretic is not justified except in the case of ineffectiveness.
Caution is advised in the administration of Paracetamol to patients with moderate and severe renal insufficiency, mild to moderate hepatocellular insufficiency (including Gilbert's syndrome), severe hepatic insufficiency *(**Child-Pugh** >**9**)*, acute hepatitis, concomitant treatment with medicinal products affecting hepatic functions, glucose-6- phosphate dehydrogenase deficiency, hemolytic anaemia, dehydration. alcohol abuse and chronic malnutrition.

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 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 MedDRA System Organ Class. Adverse reactions identified during post-marketing use are reported voluntarily from a population of uncertain size, the frequency of these reactions is unknown but likely to be very rare (<1/10,000).

PARACETAMOL

Body System	**Undesirable effect**
Blood and lymphatic system disorders	Thrombocytopenia Agranulocytosis
Immune system disorders	Very rare cases of serious skin reactions have been reported. Anaphylaxis Cutaneous hypersensitivity reactions including (amongst others) skin rashes and angioedema.
Respiratory, thoracic and mediastinal disorders	Bronchospasm- more likely in patients sensitive to aspirin and other NSAIDs
Hepatobiliary disorders	Hepatic dysfunction

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

Paracetamol
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-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.

Sodium bicarbonate
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

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SmPC.

6. Pharmaceutical particulars

6.1 List of excipients

Citric acid (Anhydrous)
Sodium bicarbonate
Sodium saccharin
Povidone-K 30
Simethicone
Aspartame
Sodium Benzoate
Sodium carbonate
Flavour Orange
Tween-80
Isopropyl alcohol
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store below 30°C

6.5 Nature and contents of the container

Alu-Alu blister pack
Pack size: 2x4

6.6 Special precautions for disposal and other handling

None

7. Marketing authorisation holder and manufacturing site addresses

Fountain Life Sciences Limited.
P.O. Box 366-00610

Nairobi

Manufacturing site address:

VOVANTIS LABORATORIES PVT. LTD.
Opp. Ranoli Railway Station,
Nr. GACL Plant, Ranoli,
Vadodara – 391 350
Gujarat, INDIA.

8. Marketing authorisation number(s)

CTD9735- Ferodol 1000mg

9. Date of first authorisation/renewal of the authorisation

Date of first authorization: 03-July-2023

10. Date of revision of the text

14-Sep-2023

11. Dosimetry:

Not Applicable

12. Instructions for preparation of radiopharmaceuticals:

Not Applicable