Summary Product Characteristics for Pharmaceutical Product

1. Name of the medicinal product

Ferodol Forte

2. Qualitative and quantitative composition

Each tablet contains Paracetamol 500.0 mg and Caffeine 65.0 mg.

Excipients with known effect

Contains 409 mg of Sodium per tablet.

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

The tablets are recommended for use as an analgesic in the relief of mild to moderate pain such as is associated with rheumatism, neuralgia, musculoskeletal disorders, headache and discomfort associated with influenza, feverishness and feverish colds, toothache and dysmenorrhoea.

4.2 Posology and method of administration

Paracetamol and caffeine-soluble tablets should be dissolved in at least half a tumblerful of water.

Adults (including the elderly) and children aged 16 years and over:
Two tablets up to four times daily.
Do not exceed 8 tablets in 24 hours.

Children aged 12-15 years:
One tablet up to four times daily.
Do not exceed 4 tablets in 24 hours.
Not recommended for children under 12 years.
Do not take more frequently than every 4 hours.
Do not take for longer than three days without consulting your doctor.

Method of Administration

Paracetamol and caffeine-soluble tablets are for oral administration only.

4.3 Contraindications

Hypersensitivity to paracetamol, caffeine or any of the other constituents.

4.4 Special warnings and precautions for use

Do not exceed the stated dose.

Contains paracetamol. Do not use with any other paracetamol-containing products. The concomitant use with other products containing paracetamol may lead to an overdose.

Paracetamol overdose may cause liver failure which may require a liver transplant or lead to death.

Care is advised in the administration of paracetamol to patients with renal or hepatic impairment. The hazard of overdose is greater in those with non-cirrhotic alcoholic liver disease.

Caution should be exercised in patients with glutathione-depleted states, as the use of paracetamol may increase the risk of metabolic acidosis (see section 4.9).

Excessive intake of caffeine (e.g. coffee, tea and some canned drinks) should be avoided while taking this product.

This medicinal product contains 818 mg sodium per dose (2 tablets) equivalent to 40.9% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

Each tablet contains sorbitol powder (E 420) at 50 mg per tablet. 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. Oral contraceptives may increase the rate of clearance of paracetamol. 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. Caffeine may increase the clearance of lithium. Concomitant use is therefore not recommended.

4.6 Pregnancy and lactation

Paracetamol-caffeine is not recommended for use during pregnancy due to the possible increased risk of lower birth weight and spontaneous abortion associated with caffeine consumption.
Caffeine in breast milk may potentially have a stimulating effect on breastfed infants.
Due to the caffeine content of this product, it should not be used if you are pregnant or 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

CAFFEINE

When the recommended paracetamol-caffeine dosing regimen is combined with dietary caffeine intake, the resulting higher dose of caffeine may increase the potential for caffeine-related adverse effects.

Body System	**Undesirable effect**
Central nervous system	Dizziness Headache
Cardiac disorders	Palpitation
Psychiatric disorders	Insomnia Restlessness

	Anxiety and irritability
Gastrointestinal disorders	Gastrointestinal disturbances

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.

Caffeine

Symptoms
Overdose of caffeine may result in epigastric pain, vomiting, diuresis, tachycardia or cardiac arrhythmia, and CNS stimulation (insomnia, restlessness, excitement, agitation, jitteriness, tremors and convulsions).
It must be noted that for clinically significant symptoms of caffeine overdose to occur with this product, the amount ingested would be associated with serious paracetamol-related toxicity.

Management
Patients should receive general supportive care (e.g. hydration and maintenance of vital signs). The administration of activated charcoal may be beneficial when performed within one hour of the overdose but can be considered for up to four hours after the overdose. The CNS effects of overdose may be treated with intravenous sedatives.

Summary
Treatment of overdose with Cope Sachets requires assessment of plasma paracetamol levels for antidote treatment, with signs and symptoms of codeine and caffeine toxicity being managed symptomatically.

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

The combination of paracetamol and caffeine is a well-established analgesic combination.

5.2 Pharmacokinetic properties

Paracetamol is rapidly and almost completely absorbed from the gastrointestinal tract. It is relatively uniformly distributed throughout most body fluids and exhibits variable protein binding. Excretion is almost exclusively renal, in the form of conjugated metabolites.

Caffeine is absorbed readily after oral administration, maximal plasma concentrations are achieved within one hour and the plasma half-life is about 3.5 hours. 65 - 80% of administered caffeine is excreted in the urine as 1-methyluric acid and 1-methylxanthine.

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) (E330)

Povidone

Saccharin Sodium

Sodium Hydrogen Carbonate (E500)

Sodium Carbonate Anhydrous

Simeticone

Polysorbate 80 (E433)

Aspartame (E951).

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)

CTD9734- Ferodol Forte

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