Ferodol 1000
(Paracetamol Effervescent Tablets BP 1000mg)

Summary Product Characteristics (SmPC)

Composition:
Each uncoated tablet contains:
Paracetamol BP 1000 mg
Excipients q.s.

1.1 Name of the medicinal product
Ferodol 1000

Qualitative and quantitative composition

COMPOSITION
Each effervescent Tablet Contains
Paracetamol BP……..1000 mg
Excipients……QS

Sr No	Material	Grade	Qty/tablet mg	% Overages added	Qty/tablet mg with Overages	Selection
PART-I						
1.	Paracetamol	BP	1000.000	0	1000.000	Active Ingredient
2.	Citric acid (Anhydrous)	BP	1261.000	10	1387.100	Effervescent System
3.	Sodium bicarbonate (Anhydrous)	BP	898.000	10	987.800	Effervescent System
4.	Sodium saccharin	BP	8.000	0	8.000	Sweetening agent
5.	PVP-K 30	USP	72.000	0	72.000	Binder
6.	Purified water	BP	0.04 ml	0	0.04ml	Solvent
PART-II						
7.	Sodium Bicarbonate	BP	300.000	0	300.000	Effervescent System
8.	Simethicone	BP	10.000	0	10.000	Antiflatulent Agent
9.	Tween-80	BP	1.000	0	1.000	Emulsifier
10	Isopropyl Alcohol	BP	0.020 ml	0	0.020 ml	Solvent
LUBRICATION						
11	Sodium Carbonate	BP	145.000	0	145.000	Effervescent System
12	Aspartame	USP	35.000	0	35.000	Sweetening agent
13	Sodium Benzoate	BP	30.000	0	30.000	Lubricating Agent
14	Flavour Orange	IH	40.000	0	40.000	Flavouring Agent
TOTAL			3800.00			

Note: - Citric Acid Anhydrous and Sodium Bicarbonate Anhydrous 10% excess added due to reaction loss in process.

Pharmaceutical form:
Effervescent Tablet

Therapeutic indications
Treatment of mild to moderate pain and/or fever.

Posology and method of administration:
Posology
This presentation is reserved for use in adults and in 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.

1.2 Contraindications:
Hypersensitivity to the active substance or to any of the excipients.

1.3 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; in such case unconsciousness does not occur. However, medical assistance should be sought immediately. 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 Gilbelt's syndrome), severe hepatic insufficiency ***(Child-Pugh* >9**), acute hepatitis, concomitant treatment with medicinal products affecting hepatic functions, glucose-6-phosphatedehydrogenase deficiency, haemolytic anaemia, dehydration. alcohol abuse and chronic malnutrition.
Do not exceed the stated dose.
If symptoms persist consult a doctor.
Treatment with an antidote is advised if an overdose is suspected.

1.4 Interaction with other medicinal products and other forms of interaction:
Hepatotoxic substances may increase the possibility of Paracetamol accumulation and overdose. The metabolization of paracetamol is increased in patients taking enzyme-inducing drugs such as rifampicin and some antiepileptics (carbamazepine, phenytoin, phenobarbital, primidone). Isolated reports describe unexpected hepatotoxicity in patients taking enzyme-inducing drugs and alcohol.
• Probenecid causes an almost 2-fold reduction in clearance of Paracetamol by inhibiting its conjugation with glucuronid acid. A reduction of the Paracetamol dose should be considered for concomitant treatment with probenecid.
• Salicylamide may prolong the elimination t1/2 of Paracetamol.
• Metoclopramide and donperidone accelerate absorption of Paracetamol.
• Cholestyramine reduces absorption of Paracetamol and therefore should not be administered within an hour following Paracetamol administration.

1.5 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/ metabolites are excreted in human milk, but at therapeutic doses of Paracetamol 1000 mg Effervescent Tablets no effects on the breastfed newborns/infants are anticipated.

Paracetamol 1000 mg Effervescent Tablets can be used during breast-feeding.

Fertility

There are no or limited amount of date from the influence of Paracetamol 1000 mg Effervescent Tablets on fertility.

1.6 Undesirable effects:

Rare: Platelet disorders, stem cell disorders, Allergies, Abnormal vision. Dizziness (excluding vertigo), malaise, pyrexia, sedation, Overdose and poisoning

Very Rare: Bronchospasm, hepatotoxicity, hypersensitivity reaction, Hypoglycemia, Sterile pyuria (cloudy urine) and renal side effects

1.7 Overdose:

There is a risk of poisoning, particularly in elderly subjects, in young children. in patients with liver disease, in cases of chronic alcoholism and in patients with chronic malnutrition. Overdose of Paracetamol is potentially fatal in all populations.

Symptoms generally appear within the first 24 hours and comprise: nausea, vomiting, anorexia, pallor, and abdominal pain. Immediate emergency measures are necessary in case of paracetamol overdose, even when no symptoms are present.

• Overdose, 10g or more of Paracetamol in adults or 150 mg/kg of body weight, causes liver cell necrosis likely to induce complete and irreversible necrosis, resulting in hepatocellular insufficiency, metabolic acidosis and encephalopathy which may lead to coma and death. Simultaneously, increased levels of hepatic transaminases (AST, AL T), lactate dehydrogenase and bilirubin are observed together with increased prothrombin levels that may appear 12 to 48 hours after administration.

2. Pharmacological properties:

2.1 Pharmacodynamic properties:

Pharmacotherapeutic group: Other analgesics and antipyretics, Anilides

ATC code N02B E01

Paracetamol has analgesic and antipyretic properties but it has no useful anti-inflammatory properties.

Paracetamol's effects are thought to be related to inhibition of prostaglandin synthesis.

2.2 Pharmacokinetic properties:

Absorption

The absorption of paracetamol by the oral route is rapid and complete. Maximum plasma concentrations are reached 30 to 60 minutes following ingestion.

Distribution

Paracetamol is distributed rapidly throughout all tissues. Concentrations are comparable in blood. saliva and plasma. Protein binding is low.

Metabolism

Paracetamol is metabolized mainly in the liver following two major metabolic pathways: glucoronic acid and sulfuric acid conjugates. The latter route is rapidly saturated at doses higher than the therapeutic dose. A minor route, catalyzed by the cytochrome P450, results in the formation of an intermediate reagent (N-acetyl-p-benzoquinoneimine) which under normal conditions of use is rapidly detoxified by glutathione and eliminated in the urine, after conjugation with cysteine and mercaptopuric acid. Conversely, when massive intoxication occurs, the quantity of this toxic metabolite is increased.

Elimination

Elimination is essentially through the urine. 90% of the ingested dose is eliminated via the kidneys within 24 hours. principally as glucuronide (60 to 80%) and sulphate conjugates (20 to 30%). Less than 5% is eliminated in unchanged form.

3. Special precautions for storage:
Do not store above 30°C. Store in a dry place. Protect from direct sunlight.
KEEP MEDICINES OUT OF REACH OF CHILDREN.

4. Presentation:
2 X 4 Tablets

Marketed By :
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Manufacturer:
VOVANTIS LABORATORIES PVT. LTD.
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