Summary of Product Characteristics
OPTIMOL-M
(Paracetamol 125 mg and mefenamic acid 50 mg per 5 mL oral suspension)

---

1. Name of the medicinal product

OPTIMOL-M (Paracetamol and Mefenamic Acid Oral Suspension)

2. Qualitative and quantitative composition

Each 5 mL of oral suspension contains paracetamol 125 mg and mefenamic acid 50 mg.

Excipients with known effect:

The finished-product excipients (which may include sucrose, sorbitol, propylene glycol, parabens or a colouring agent) were not itemised in the source registration record; any excipient of known effect present must be declared here and warned in section 4.4 (see section 6.1).

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Oral suspension.

A light-orange, flavoured suspension.

4. Clinical particulars

4.1 Therapeutic indications

OPTIMOL-M is indicated for the symptomatic relief of mild to moderate pain, including abdominal and menstrual cramps, and for the reduction of fever, where combined analgesic, antipyretic and anti-inflammatory (antispasmodic) action is appropriate.

4.2 Posology and method of administration

Posology

The dose should be determined according to the child's body weight and age, and the lowest effective dose used for the shortest duration necessary to control symptoms. A usual guide is a paracetamol dose of 10–15 mg/kg and a mefenamic acid dose of approximately 6.5 mg/kg per dose, given up to three times daily. The dose should not be repeated more frequently than every 6 hours, and the maximum number of doses in 24 hours should not be exceeded. Treatment should not continue for more than 7 days without medical review. Precise per-dose volumes should be confirmed against the applicant's approved dosing schedule for this strength.

Paediatric population

Mefenamic-acid-containing products are generally not recommended in children under 6 months; use in young children should be under medical supervision.

Method of administration

For oral use. Shake well before use. It is preferable to give the suspension with or after food to reduce gastrointestinal upset.

4.3 Contraindications

- Hypersensitivity to paracetamol, mefenamic acid or to any of the excipients listed in section 6.1.
- Patients in whom acetylsalicylic acid or other NSAIDs precipitate asthma, urticaria or acute rhinitis.
- Active, or history of, peptic ulceration, gastrointestinal bleeding or perforation, and inflammatory bowel disease (ulcerative colitis, Crohn's disease).
- Severe hepatic or renal impairment, and severe heart failure.
- Third trimester of pregnancy.

4.4 Special warnings and precautions for use

The lowest effective dose should be used for the shortest duration. Mefenamic acid, like other NSAIDs, can cause serious gastrointestinal events (bleeding, ulceration, perforation) and may be associated with a small increased risk of arterial thrombotic events; caution is required in patients with cardiac, hepatic or renal impairment, in the dehydrated, and in the elderly. Diarrhoea (sometimes with rash) is a recognised effect of mefenamic acid and warrants discontinuation. Serious skin reactions (Stevens-Johnson syndrome, toxic epidermal necrolysis, AGEP) have been reported with NSAIDs; the medicine should be withdrawn at the first appearance of skin rash, mucosal lesions or any other sign of hypersensitivity, and not re-introduced. Convulsions may occur in mefenamic acid overdose.

Paracetamol – risk of hepatotoxicity

Doses of paracetamol higher than those recommended may cause serious, potentially fatal, liver damage. Care is advised in patients with hepatic or renal impairment, dehydration or chronic malnutrition. Patients should not take other paracetamol-containing products concurrently, and immediate medical advice should be sought in the event of an overdose, even if the patient feels well.

4.5 Interaction with other medicinal products and other forms of interaction

Mefenamic acid may increase the plasma concentrations of lithium and methotrexate, may enhance the effect of anticoagulants, may reduce the effect of diuretics and antihypertensives, and may increase the nephrotoxicity of ciclosporin; concomitant use with other NSAIDs or corticosteroids increases the risk of gastrointestinal adverse effects. The anticoagulant effect of warfarin may be enhanced by prolonged regular use of paracetamol; the risk of paracetamol toxicity may be increased by enzyme-inducing agents (e.g. rifampicin, anticonvulsants) and chronic alcohol. Metoclopramide increases, and cholestyramine reduces, the absorption of paracetamol.

4.6 Fertility, pregnancy and lactation

Pregnancy

From the 20th week of gestation, NSAID use may cause oligohydramnios and premature constriction of the ductus arteriosus; mefenamic acid is contraindicated during the third trimester. During the first and second trimesters it should not be given unless clearly necessary. Paracetamol may be used during pregnancy at the lowest effective dose if clinically needed.

Breast-feeding

Both actives are excreted in breast milk in small amounts; the product is not recommended during breast-feeding unless the benefit outweighs the risk.

Fertility

The use of NSAIDs may impair female fertility and is not recommended in women attempting to conceive; the effect is reversible on withdrawal.

4.7 Effects on ability to drive and use machines

The product may cause dizziness, drowsiness or visual disturbance; affected patients should not drive or operate machinery.

4.8 Undesirable effects

The adverse reactions are listed below by System Organ Class and frequency, defined as: common (≥1/100 to <1/10), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000) and not known (cannot be estimated from the available data). Reactions attributed to mefenamic acid are tagged (M) and those to paracetamol (P).

System Organ Class	Frequency	Adverse reaction
Blood and lymphatic system disorders	Not known	Thrombocytopenia, agranulocytosis, leucopenia, neutropenia, haemolytic anaemia, aplastic anaemia (M/P)
Immune system disorders	Rare	Hypersensitivity reactions, urticaria, angioedema, anaphylaxis (M/P)
Nervous system disorders	Common	Headache, dizziness, drowsiness, nervousness (M)
Eye disorders	Not known	Visual disturbance (M)
Ear and labyrinth disorders	Not known	Tinnitus (M)
Respiratory, thoracic and mediastinal disorders	Very rare	Bronchospasm in patients sensitive to aspirin and other NSAIDs (M)
Gastrointestinal disorders	Common	Diarrhoea, nausea, vomiting, abdominal pain, dyspepsia (M)
	Not known	Peptic ulceration, gastrointestinal bleeding and perforation, colitis, pancreatitis (M)
Hepatobiliary disorders	Rare	Abnormal liver function tests, hepatitis (M); hepatic dysfunction, especially in overdose (P)
Skin and subcutaneous tissue disorders	Rare	Rash, pruritus (M/P)
	Not known	Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis and acute generalised exanthematous pustulosis; photosensitivity (M/P)
Renal and urinary disorders	Not known	Acute renal failure, interstitial nephritis, haematuria (M)
General disorders and administration site conditions	Rare	Fatigue, malaise (M)

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 to the National Regulatory Authority.

4.9 Overdose

Paracetamol overdose may cause serious, potentially fatal, hepatocellular necrosis; the antidote N-acetylcysteine should be administered without delay according to the plasma paracetamol concentration and the time since ingestion. Mefenamic acid overdose may cause gastrointestinal effects and, characteristically, convulsions; treatment is symptomatic and supportive, with activated charcoal within one hour of ingestion of a potentially toxic amount, and control of convulsions as required.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other analgesics and antipyretics, anilides; paracetamol, combinations excluding psycholeptics. ATC codes: paracetamol combinations N02BE51; mefenamic acid M01AG01.

Paracetamol has analgesic and antipyretic properties mediated centrally through inhibition of prostaglandin synthesis and action on the hypothalamic heat-regulating centre. Mefenamic acid is a non-steroidal anti-inflammatory drug of the fenamate class with analgesic, anti-inflammatory and antipyretic activity, acting by inhibition of cyclo-oxygenase and prostaglandin synthesis and, additionally, by antagonism of prostaglandin at the receptor. The combination provides complementary analgesic and antipyretic activity with an anti-inflammatory/antispasmodic component useful in cramping pain.

5.2 Pharmacokinetic properties

Paracetamol

Paracetamol is rapidly and almost completely absorbed, with peak plasma concentrations within about 0.5 to 1 hour; it is metabolised predominantly in the liver by conjugation, and excreted in the urine mainly as glucuronide and sulphate conjugates, with a plasma half-life of 2–3 hours.

Mefenamic acid

Mefenamic acid is absorbed from the gastrointestinal tract, is highly bound to plasma proteins, is metabolised in the liver by oxidation and conjugation, and is excreted in the urine and faeces; the elimination half-life is approximately 2 to 4 hours.

5.3 Preclinical safety data

Paracetamol and mefenamic acid are well-established active substances. Non-clinical data reveal no special hazard for humans beyond that reflected in other sections of this Summary of Product Characteristics; as expected for an NSAID, mefenamic acid produced gastrointestinal and renal effects in animals at high doses.

6. Pharmaceutical particulars

6.1 List of excipients

The full quantitative list of excipients was not provided in the source registration record and should be inserted verbatim from the applicant's finished-product formulation (3.2.P.1). For an oral suspension of this type, any sucrose, sorbitol, propylene glycol, paraben preservatives or colouring agent present are excipients of known effect and must be declared in section 2 and warned in section 4.4.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

To be confirmed from the applicant's stability data. After first opening, the in-use shelf life should be stated per the approved label.

6.4 Special precautions for storage

Store below 30°C. Protect from light. Do not freeze. Keep out of the reach and sight of children.

6.5 Nature and contents of container

60 mL of suspension in an amber PET bottle, presented in a carton together with a measuring device and the package insert.

6.6 Special precautions for disposal and other handling

Shake well before use.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing Authorisation Holder and Manufacturer

Ravenbhel Healthcare Pvt. Ltd., 16-17, EPIP, SIDCO, Kartholi Bari-Brahmana, Jammu-181133, India.

8. Marketing Authorisation Number

H2022/CTD9260/15229

9. Date of first authorisation / renewal of the authorisation

10. Date of revision of the text