

Plomatch P Tablet

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Composition:

Each film-coated tablet contains:

- **Polmacoxib IP** – 2 mg
- **Paracetamol IP** – [Specify strength, e.g., 500 mg]*
- **Excipients** – q.s.
- **Colour** – Approved colour used

(*Please confirm Paracetamol strength if not standardized.)

Dosage Form:

Tablet

Therapeutic Category:

NSAID and Analgesic – For Pain and Inflammation

Pharmacology & Mechanism of Action:

Polmacoxib is a novel selective COX-2 inhibitor that offers effective anti-inflammatory and analgesic action with a reduced risk of gastrointestinal side effects compared to traditional NSAIDs. It has a dual mechanism – selectively inhibiting COX-2 and weakly inhibiting carbonic anhydrase, contributing to its improved cardiovascular safety profile.

Paracetamol (Acetaminophen) acts centrally by inhibiting prostaglandin synthesis in the CNS, producing analgesic and antipyretic effects without significant anti-inflammatory activity.

Indications:

- Acute and chronic pain associated with osteoarthritis, rheumatoid arthritis, or musculoskeletal disorders
- Fever associated with inflammatory conditions
- Post-operative or traumatic pain
- Pain management in cases requiring both anti-inflammatory and antipyretic action

Dosage and Administration:

- **Adults:** 1 tablet once or twice daily or as directed by the physician
- To be taken after meals with sufficient water
- Dose adjustment may be needed in hepatic or renal impairment

Contraindications:

- Hypersensitivity to Polmacoxib, Paracetamol, or any component of the formulation
- Active gastrointestinal bleeding or peptic ulcers

- Severe hepatic or renal dysfunction
- Pregnancy (especially 3rd trimester) and lactation unless prescribed

Warnings and Precautions:

- Use cautiously in patients with cardiovascular disease, hypertension, or history of GI bleeding
- Monitor liver function with prolonged Paracetamol use
- Avoid concomitant use with other NSAIDs or Paracetamol-containing products
- Not recommended in children unless specifically advised by a physician

Drug Interactions:

- Increased risk of hepatotoxicity with alcohol or enzyme inducers
- May reduce the efficacy of antihypertensives
- Anticoagulants (e.g., warfarin) may have enhanced effects with Paracetamol
- Avoid combination with other COX-2 inhibitors or nephrotoxic drugs

Adverse Effects:

- Common: Nausea, dizziness, abdominal pain, dyspepsia
- Rare: Elevation in liver enzymes, hypersensitivity reactions, fluid retention
- Serious: GI bleeding, hepatotoxicity (with overdose or long-term use)

Overdose:

Paracetamol overdose may cause severe liver damage.

Symptoms include nausea, vomiting, lethargy, and right upper quadrant pain.

Treatment includes gastric lavage and administration of **N-acetylcysteine** as an antidote within 8–10 hours.

Polmaxcoxib overdose should be managed with supportive therapy.

Storage:

Store below 25°C in a dry, well-ventilated place

Protect from direct sunlight and moisture

Keep out of reach of children

Manufactured in India for:



Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

Plot no.: 367-FF, Industrial Area Phase-I,

Panchkula-134113

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