

Information For the User
Ibuprofen (400mg) + Paracetamol (325mg) Tablet

Ibutyle P Tablet

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Composition:

Each film-coated tablet contains:

- **Ibuprofen IP** – 400 mg
- **Paracetamol IP** – 325 mg
- **Excipients** – q.s.
- **Colour:** Approved colour used

Dosage Form:

Tablet

Therapeutic Category:

Nonsteroidal Anti-inflammatory Drug (NSAID) + Analgesic & Antipyretic Combination

Pharmacology & Mechanism of Action:

Ibuprofen is a non-selective NSAID that inhibits cyclooxygenase enzymes (COX-1 and COX-2), thereby decreasing the synthesis of prostaglandins involved in pain, inflammation, and fever.

Paracetamol acts primarily in the central nervous system, inhibiting COX enzymes and elevating the pain threshold. It also exerts antipyretic effects by acting on the hypothalamic heat-regulating center.

This combination provides synergistic analgesic, antipyretic, and anti-inflammatory action with faster and more prolonged relief compared to individual drugs.

Indications:

- Mild to moderate pain of musculoskeletal origin
- Headache, dental pain, backache
- Fever associated with cold, flu, or infections
- Dysmenorrhea
- Inflammatory conditions such as arthritis

Dosage & Administration:

- **Adults and children above 12 years:** 1 tablet every 6 to 8 hours as needed
- **Maximum daily dose:** Do not exceed 3 tablets in 24 hours unless advised by a physician
- To be taken after food with water to reduce gastrointestinal side effects

Contraindications:

- Hypersensitivity to ibuprofen, paracetamol, or any excipients
- Active or history of peptic ulcer, GI bleeding, or perforation

- Severe hepatic, renal, or cardiac impairment
- Asthma or allergic reactions triggered by NSAIDs
- Concomitant use with other NSAIDs or paracetamol-containing products

Warnings & Precautions:

- Use with caution in patients with hypertension, diabetes, liver or kidney dysfunction
- Avoid alcohol during therapy due to risk of liver toxicity
- Long-term use not recommended without medical supervision
- Monitor liver function in prolonged usage

Drug Interactions:

- Increased risk of bleeding with anticoagulants (e.g., warfarin)
- May reduce efficacy of antihypertensives and diuretics
- Enhanced hepatotoxicity with other paracetamol-containing products or alcohol
- Avoid concurrent use with methotrexate or lithium

Adverse Effects:

- Common: Nausea, dyspepsia, abdominal pain, heartburn
- Occasional: Dizziness, rash, drowsiness

Overdose:

- **Paracetamol overdose** may cause severe liver damage. Early symptoms include nausea, vomiting, and abdominal pain.
- **Ibuprofen overdose** may lead to drowsiness, headache, hypotension, renal failure.
- Immediate medical attention and supportive care are essential. N-acetylcysteine may be used as an antidote for paracetamol toxicity.

Storage:

Store below 25°C in a dry, cool place
Protect from direct sunlight and moisture

Manufactured in India for:

CafoliTM
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Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

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