

Para-AL 500

(Paracetamol 500 mg)

Each tablet contains:

Paracetamol IP.....500 mg

Excipients.....q.s.

Clinical Pharmacology: Paracetamol (acetaminophen) primarily works in the central nervous system (CNS) by inhibiting the synthesis of prostaglandins, which are chemicals involved in pain and inflammation. It is believed to primarily inhibit the enzyme cyclooxygenase (COX), although its exact mechanism remains not fully understood. Paracetamol has analgesic (pain-relieving) and antipyretic (fever-reducing) properties, but it has minimal anti-inflammatory effects.

Indications:

- **Pain Relief:**
- Mild to moderate pain, including:
 - Headaches
 - Toothaches
 - Muscle aches
 - Menstrual cramps
 - Arthritis pain
- **Fever Reduction:**
- Management of fever associated with various conditions, including infections.

Contraindications:

- **Hypersensitivity:** Contraindicated in individuals with a known allergy to paracetamol or any of its components.
- **Severe Liver Disease:** Avoid use in patients with severe hepatic impairment or active liver disease, as paracetamol can exacerbate liver damage.
- **Severe Renal Impairment:** Caution is advised in patients with significant renal dysfunction, as dosing adjustments may be necessary.
- **Alcohol Use:** Chronic alcohol abuse can increase the risk of hepatotoxicity, so caution is warranted in heavy drinkers.

Precautions:

- **Liver Function:** Use with caution in patients with liver disease or impaired liver function. Dosage adjustments may be necessary.
- **Alcohol Consumption:** Patients who consume alcohol regularly should be cautious, as chronic use can increase the risk of liver toxicity.
- **Renal Function:** Monitor renal function in patients with existing renal impairment, as dosing may need adjustment.
- **Long-term Use:** Prolonged use at high doses can increase the risk of liver damage. Limit use to recommended doses and durations.
- **Allergic Reactions:** Be aware of potential allergic reactions, including skin rashes or anaphylaxis, though these are rare.

Cautions:

- **Other Medications:** Caution is advised when used in combination with other medications that can affect liver function or have hepatotoxic potential.
- **Pregnancy and Breastfeeding:** While generally considered safe, consult a healthcare provider before use during pregnancy or breastfeeding.
- **Symptoms of Overdose:** Educate patients about the signs of overdose (e.g., nausea, vomiting, loss of appetite, confusion) and the importance of seeking medical attention immediately.
- **Children:** Dosage must be appropriate for age and weight in pediatric patients; always follow pediatric dosing guidelines.

Drug Interactions:

- **Warfarin and Other Anticoagulants:** Chronic use of paracetamol may enhance the anticoagulant effect of warfarin, increasing the risk of bleeding. Monitor INR levels closely.
- **Alcohol:** Concurrent consumption of alcohol can increase the risk of liver toxicity, particularly with regular or excessive intake.
- **Antiepileptics:** Certain medications (e.g., phenytoin, carbamazepine) may increase the metabolism of paracetamol, potentially reducing its effectiveness and increasing the risk of toxicity.
- **Other Hepatotoxic Drugs:** Use caution when combining with medications known to cause liver damage (e.g., isoniazid), as this may increase the risk of hepatotoxicity.
- **Rifampicin:** This antibiotic can induce liver enzymes, leading to reduced effectiveness of paracetamol.
- **Certain Antibiotics:** Some antibiotics (e.g., chloramphenicol) may interact, potentially affecting paracetamol metabolism.

Adverse Effects:

Common Adverse Effects:

1. **Gastrointestinal:**
 - Nausea
 - Vomiting
 - Abdominal pain
2. **General:**
 - Fatigue
 - Malaise

Serious Adverse Effects:

1. **Hepatotoxicity:**
 - Liver damage, which can manifest as elevated liver enzymes, jaundice, or hepatic failure, particularly in cases of overdose or prolonged use.
2. **Allergic Reactions:**
 - Rarely, severe allergic reactions such as anaphylaxis or skin reactions (e.g., rash, Stevens-Johnson syndrome).
3. **Renal Effects:**
 - Acute kidney injury has been reported in rare cases, particularly with prolonged use.
4. **Skin Reactions:**
 - Potential for serious skin reactions, including rashes and other hypersensitivity reactions.

Overdosage:

Symptoms:

- **Initial Symptoms** (within the first 24 hours):
 - Nausea
 - Vomiting
 - Loss of appetite
 - Confusion
 - Abdominal pain (particularly in the upper right quadrant)
- **Later Symptoms** (24 to 72 hours):
 - Elevated liver enzymes (ALT, AST)
 - Jaundice (yellowing of the skin and eyes)
 - Hepatic failure, which can lead to complications such as coagulopathy, renal failure, and metabolic acidosis.

Management:

1. **Seek Immediate Medical Attention:** Overdose is a medical emergency. Contact a healthcare provider or poison control center immediately.
2. **Activated Charcoal:** If the overdose is identified soon after ingestion, activated charcoal may be administered to limit absorption, provided the patient is alert and not at risk of aspiration.

3. **N-Acetylcysteine (NAC):** This is the antidote for paracetamol overdose and is most effective when given within 8 to 10 hours of ingestion. It works by replenishing glutathione levels in the liver, thereby preventing liver damage.
4. **Monitoring:** Continuous monitoring of liver function tests and other vital signs is critical in a healthcare setting.

Route of Administration: Oral.

Dosage: As directed by the physician.

Storage: Store below 25°C. Keep the medicine out of reach of children.

Presentation: It is available as 500mg 10x10 tablets.

