

(Loperamide 2 Tablet)

Each tablet contains: Loperamide.....2 mg Excipients.....q.s

Clinical Pharmacology:

Loperamide: Loperamide is an opioid receptor agonist that primarily acts on the μ opioid receptors in the gut. It slows down gastrointestinal motility, leading to increased transit time and enhanced absorption of fluids and electrolytes. This results in reduced stool frequency and improved consistency.

Indications:

- Acute Diarrhea: Loperamide is used to manage acute nonspecific diarrhea, providing symptomatic relief and reducing stool frequency.
- **Chronic Diarrhea**: It is indicated for chronic diarrhea associated with conditions such as:
- Inflammatory bowel disease (e.g., Crohn's disease, ulcerative colitis).
- Non-infectious diarrhea.
- **Traveler's Diarrhea**: Loperamide may be used to alleviate symptoms of diarrhea during travel, particularly when symptoms are mild to moderate.

Contraindications:

- **Hypersensitivity**: Contraindicated in individuals with known hypersensitivity to loperamide or any of its components.
- Acute Dysentery: Loperamide should not be used in cases of acute dysentery, characterized by blood in the stools and high fever.
- **Bacterial Enterocolitis**: Contraindicated in conditions caused by certain bacteria (e.g., Salmonella, Shigella) as it may worsen the infection.
- **Pseudomembranous Colitis**: Use is contraindicated in patients with a history of pseudomembranous colitis associated with antibiotic use.
- Severe Liver Disease: Caution is advised in patients with severe hepatic impairment, as metabolism may be affected.
- Abdominal Pain without Diarrhea: Should not be used in patients with abdominal pain without diarrhea, as this could mask underlying conditions.

Precautions:

- **Underlying Conditions:** Use with caution in patients with liver disease, as impaired metabolism may lead to increased side effects.
- **Chronic Diarrhea:** Patients with chronic diarrhea should be evaluated for underlying conditions before using loperamide.
- Fluid and Electrolyte Imbalance: Monitor for dehydration and electrolyte imbalance, especially in cases of severe diarrhea.
- **CNS Effects**: Use caution in individuals with a history of central nervous system disorders, as loperamide can cause sedation and dizziness.
- **Pregnancy and Breastfeeding**: Consult a healthcare provider before use if pregnant or breastfeeding, as the safety profile in these populations is not fully established.
- Warnings:
- **Toxic Megacolon**: Use with caution in patients with conditions that predispose them to toxic megacolon (e.g., ulcerative colitis).
- **Paralytic Ileus**: May occur with excessive doses; discontinue use if constipation or abdominal distention develops.
- **Serious Allergic Reactions**: Be aware of potential severe allergic reactions, including anaphylaxis. Seek medical attention if signs occur.
- **Drug Interactions**: Use caution with medications that may affect loperamide metabolism or enhance its effects (e.g., certain antidepressants and other CNS depressants).

Drug Interactions:

- CYP3A4 Inhibitors:
- Medications that inhibit CYP3A4 (e.g., ketoconazole, itraconazole) can increase loperamide levels, potentially leading to increased side effects or toxicity.
- CYP2C8 Inhibitors:
- Drugs that inhibit CYP2C8 may also affect loperamide metabolism, necessitating caution and potential dosage adjustments.
- Central Nervous System (CNS) Depressants:
- Concurrent use with other CNS depressants (e.g., alcohol, benzodiazepines, opioids) can enhance sedation and respiratory depression.
- Digoxin:
- Loperamide may increase the absorption of digoxin, leading to higher plasma concentrations and a potential risk of toxicity.
- Anticholinergic Drugs:

- Combining with anticholinergic medications may exacerbate constipation or other gastrointestinal effects.
- Other Antidiarrheals:
- Caution is advised when using loperamide with other antidiarrheal medications, as this can increase the risk of constipation and bowel obstruction.

Serious Adverse Effects

- Allergic Reactions: Severe allergic reactions, including anaphylaxis
- **Cardiovascular Effects:** Prolonged QT interval, which can lead to serious heart rhythm disturbances, particularly in high doses.
- **CNS Effects:** Sedation or drowsiness, especially when used with other CNS depressants.
- **Toxic Megacolon**: Risk in patients with inflammatory bowel disease or those with a history of toxic megacolon.
- **Paralytic Ileus**: May occur with excessive doses; symptoms include abdominal distention and severe constipation.

Overdosage:

Symptoms:

Gastrointestinal: Nausea, vomiting, constipation, and abdominal discomfort.

Central Nervous System: Dizziness, drowsiness, fatigue, and in severe cases, confusion or respiratory depression.

Cardiovascular: Potential for prolonged QT interval, which can lead to arrhythmias. **Management**:

Seek Medical Attention: If overdose is suspected, it is crucial to contact a healthcare provider or poison control center immediately.

Supportive Care: There is no specific antidote for loperamide overdose. Treatment typically focuses on supportive measures, including monitoring vital signs and providing symptomatic relief.

Activated Charcoal: In some cases, activated charcoal may be administered if the overdose is recent and the patient is alert.

Monitoring: Continuous monitoring of cardiac function may be necessary due to the risk of arrhythmias.

Dosage: As prescribed by Physician.

Storage: Store in a cool, dry place away from direct sunlight and moisture. Keep out of reach of children.

Presentation: It is available as 10x10 packaging.

