Information For the Use
Ondansetron (2mg) + Ranitidine (25mg)

Ranilair O Injection

Ondansetron (2 mg) + Ranitidine (25 mg) Injection

Category: Combination Therapy – Anti-emetic and Antacid
Dosage Form: Sterile injection

Description

This combination of Ondansetron, a serotonin 5-HT3 receptor antagonist, and Ranitidine, a histamine H2 receptor antagonist, is used to treat and prevent nausea, vomiting, and gastric acid-related conditions. Ondansetron is highly effective in preventing nausea and vomiting caused by chemotherapy, radiation, and surgery, while Ranitidine reduces gastric acid secretion and helps manage conditions such as acid reflux, ulcers, and gastroesophageal reflux disease (GERD). This combination is particularly beneficial for patients undergoing surgical procedures or chemotherapy who are at risk for both nausea and acid reflux.

Composition (Per mL):

- **Ondansetron: 2 mg**
- **Ranitidine: 25 mg**

Indications:

1. **Chemotherapy-Induced Nausea and Vomiting (CINV):**
    - **Prevents acute and delayed nausea and vomiting associated with cancer chemotherapy.**
2. **Radiotherapy-Induced Nausea and Vomiting (RINV):**
    - **Prevents nausea and vomiting caused by radiation therapy.**
3. **Post-Operative Nausea and Vomiting (PONV):**
    - **Prophylaxis and treatment of nausea and vomiting following surgery.**
4. **Gastric Acidity and GERD:**
    - **Manages excess gastric acid production and prevents acid reflux, heartburn, and stomach ulcers.**
5. **Peptic Ulcer Disease:**
    - **Reduces acid secretion and promotes healing of peptic ulcers.**

Dosage and Administration:

- **Adults:**
    - **Chemotherapy-Induced Nausea/Vomiting (CINV) and Post-Operative Nausea/Vomiting (PONV): Administer 1–2 mL (2–4 mg Ondansetron) + 1–2 mL (25–50 mg Ranitidine) intravenously, either as a single dose before chemotherapy or surgery, or as needed post-procedure.**
    - **Gastric Acid Conditions (e.g., GERD, Peptic Ulcers): Administer 1–2 mL (2–4 mg Ondansetron) + 1–2 mL (25–50 mg Ranitidine) once or**

twice a day, as directed by the healthcare provider.

Administration Instructions:

- **Administer by slow intravenous injection over 2–5 minutes.**
- **Dilution may be required for certain patients; refer to product-specific guidelines for dilution details.**

Mechanism of Action:

- **Ondansetron:**
  - **Blocks the action of serotonin at the 5-HT3 receptors located in the central nervous system (CNS) and gastrointestinal (GI) tract. This prevents the initiation of nausea and vomiting signals in response to chemotherapy, radiation, or surgery.**
- **Ranitidine:**
  - **Inhibits the action of histamine at H2 receptors in the stomach lining, thereby reducing the production of gastric acid. This helps alleviate symptoms associated with acid reflux, ulcers, and GERD.**

Pharmacokinetics:

- **Ondansetron:**
  - **Absorption: Rapidly absorbed following IV administration.**
  - **Half-life: Approximately 3–6 hours.**
  - **Metabolism: Primarily metabolized in the liver via CYP450 enzymes.**
- **Ranitidine:**
  - **Absorption: Rapidly absorbed, with peak plasma levels occurring 2–3 hours after administration.**
  - **Half-life: Approximately 2–3 hours.**
  - **Metabolism: Undergoes minimal hepatic metabolism, with most of the drug excreted unchanged in the urine.**

Contraindications:

- **Ondansetron:**
  - **Hypersensitivity to Ondansetron or any of its components.**
  - **Concomitant use with apomorphine (due to the risk of hypotension and loss of consciousness).**
- **Ranitidine:**
  - **Hypersensitivity to Ranitidine or any components of the formulation.**
  - **Patients with acute porphyria.**

Warnings and Precautions:

1. **Ondansetron:**
   - **Use with caution in patients with a history of cardiac arrhythmias or electrolyte imbalances (e.g., hypokalemia, hypomagnesemia).**
   - **May cause serotonin syndrome when used in combination with other serotonergic agents.**
2. **Ranitidine:**
   - **Prolonged use may mask symptoms of gastric cancer;**

should be used with caution in patients with gastric ulcers.
    - Discontinue use if symptoms worsen or persist.
3. **Renal Impairment:**
    - Adjust dosages accordingly in patients with impaired renal function.
4. **Pregnancy and Lactation:**
    - Ondansetron: Use only if clearly needed during pregnancy, as it crosses the placental barrier.
    - Ranitidine: Use with caution during pregnancy; secreted in breast milk.

Adverse Effects:

- **Common Side Effects:**
    - Headache, constipation, dizziness, and fatigue.
    - Nausea, abdominal discomfort, or mild gastrointestinal disturbances.
- **Serious Side Effects:**
    - Rare: QT prolongation, arrhythmias, hypersensitivity reactions, and anaphylaxis.
    - Rare: Hepatic enzyme abnormalities, jaundice, or hepatotoxicity (more common with prolonged use of Ranitidine).

Storage Instructions:

- Store at room temperature (15–25°C).
- Protect from light and freezing.
- Keep out of reach of children.

Key Points for Use:

- For Post-Operative Use: Administer before anesthesia induction to prevent post-operative nausea and vomiting.
- For Chemotherapy and Radiotherapy Use: Administer Ondansetron and Ranitidine at least 30 minutes before chemotherapy or radiation therapy.
- Ensure adequate hydration, especially in patients undergoing chemotherapy, to help prevent dehydration from vomiting.

Note: This product should be used under medical supervision, and regular monitoring for side effects, particularly for patients with pre-existing heart conditions or kidney impairment, is recommended.

Manufactured in India for:

Cafoli Lifecare Pvt. Ltd.
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