Sulmetic™

Amisulpride

Presentation

Sulmetic™ IV Injection: Each 2ml injectable solution contains Amisulpride BP 5 mg.

Description

Amisulpride is a selective dopamine-2 (D_2) and dopamine-3 (D_3) receptor antagonist. D_2 receptors are located in the chemoreceptor trigger zone (CTZ) and respond to the dopamine released from the nerve endings. Activation of CTZ relays stimuli to the vomiting center which is involved in emesis. Studies in multiple species indicate that D_3 receptors in the postrema area also play a role in emesis. Studies have also shown that amisulpride inhibits emesis caused by apomorphine, with an estimated ED_{50} of less than 1 mcg/kg, subcutaneously; and inhibits cisplatin-induced emesis at 2 mg/kg and morphine-induced emesis at 3 to 6 mg/kg, when given intravenously.

Indications

Sulmetic IV Injection is indicated in adults for the following conditions:

1.Prevention of postoperative nausea and vomiting (PONV): Either alone or in combination with another antiemetic of a different class.

2. Treatment of postoperative nausea and vomiting (PONV): In patients who have received antiemetic prophylaxis of a different class or have not received prophylaxis.

Dosage and Administration

Indications	Dosage	Route of administration
Prevention of postoperative nausea and vomiting (PONV)	5 mg as a single dose infused over 1 to 2 minutes at the time of induction of anesthesia.	Intravenous
Treatment of postoperative nausea and vomiting (PONV)	10 mg as a single dose infused over 1 to 2 minutes after a surgical procedure.	Intravenous

Preparation

Dilution is not required before administration of Sulmetic IV Injection. It should be administered within 12 hours of removal of the vial from the protective carton.

Contraindications

Amisulpride is contraindicated in patients with known hypersensitivity to any of its components.

Precautions

Amisulpride causes dose-and concentration-dependent prolongation of the QT interval. Avoid Amisulpride in patients with congenital long QT syndrome and in patients taking droperidol. Electrocardiogram (ECG) monitoring is recommended in patients with pre-existing arrhythmia/cardiac conduction disorders; electrolyte abnormalities; congestive heart failure; and in patients taking other medicinal products (e.g., ondansetron) or with other medical conditions known to prolong the QT interval.

Side Effects

Most common adverse reactions (≥ 2%) are:

- Prevention of PONV: increased blood prolactin concentrations, chills, hypokalemia, procedural hypotension, and abdominal distension.
- Treatment of PONV: infusion site pain.
- Rare side-effects: Agranulocytosis, bradycardia, angioedema, urticaria, hypotension

Drug Interactions

- **Dopamine Agonist:** Avoid using levodopa with Amisulpride.
- **Drugs Prolonging the QT Interval**

To avoid potential additive effects, avoid use of Amisulpride in patients taking droperidol. ECG monitoring is recommended in patients taking other drugs known to prolong the QT interval (e.g., ondansetron).

Use in Pregnancy and Lactation

Available data with Amisulpride use in pregnant women are insufficient to establish a drug associated risk.

Overdose

Overdose data of Amisulpride injection is not available.

Storage

Do not store above 30 °C. Keep away from light and out of the reach of children.

Commercial Packaging

Sulmetic™ IV Injection: Each box contains one vial of 2 ml IV injection and a leaflet.

Manufactured by
Incepta Pharmaceuticals Ltd
Dhamrai Unit, Dhaka, Bangladesh
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V.N.01

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