La Renon

# Sultaren

Amisulpride Injection 5 mg/2 ml

Subdue The

*After Effects*

1st TIME In India

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## Post-Operative Nausea And Vomiting (PONV)[1]

### In High Risk Patients


Can Experience **PONV**

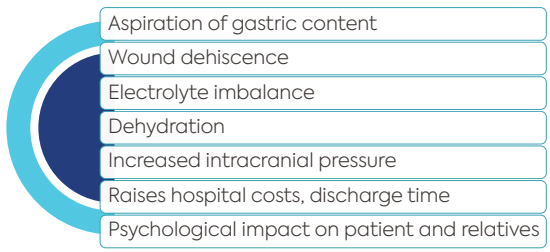
Can Experience **PONV despite prophylaxis**

### In Patients who failed Prophylaxis


Can Experience **Nausea**

Can Experience **Vomiting**

## Consequences Of PONV[2]




## PONV is a Common Complication of Surgery and Anesthesia Despite Prophylaxis

## Unmet Needs In The Management Of PONV

**Despite Current Treatment Options, PONV Is Not Adequately Controlled [3]**

**Current PONV Therapy Shortfall [4,5,6,7,8]**

| Drugs | Side effects |
|---|---|
| Ondansetron | QT prolongation |
| Dexamethasone | Slow to take effect |
| Droperidol | Risk of Torsade de pointes |

**Fourth consensus guidelines (2020) for the management of postoperative nausea and vomiting recommends [9]**

1. No single drug or class of drug is completely effective.
2. Multimodal prophylaxis reduces PONV incidence.
3. A better prophylaxis might be achieved by using a combination of agents acting at different receptor sites

**Need of new generation $D_2$ & $D_3$ receptor antagonist with minimal side effects [4]**

## INTRODUCING DOPAMINE ANTAGONIST AS NOVEL ANTI-EMETIC

- Amisulpride is 1st ever drug to be approved by USFDA for both prophylaxis & treatment of PONV (26 February 2020)
- It is Recently approved by DCGI (May 2023)

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## AMISULPRIDE INJECTION IS SAFE AND EFFECTIVE FOR PONV

- **As Monotherapy Prophylaxis**
- **As Combination Prophylaxis: With Dexamethasone/ Ondansetron**
- **As Treatment Option With No Prior Prophylaxis**
- **As Treatment Option With Failed Prior Prophylaxis** [4,6,10,11]

## Safety Data

- Intravenous Amisulpride Does Not Meaningfully Prolong the QTc Interval at Doses Effective for the Management of Postoperative Nausea and Vomiting.
- Amisulpride showed no evidence of the toxicities associated with other commonly used antiemetics, notably cardiac and extrapyramidal events, constipation, sedation, infection and diabetogenesis, all of which are potential concerns in the early postoperative period.[12, 13, 14]

## Combination Therapy Prophylaxis

**Amisulpride Prevents Postoperative Nausea and Vomiting in Patients at High Risk**

**Type of Study:** A double-blind, randomized, placebo-controlled, international, multicenter trial

**Subjects:** 1147 adult surgical patients

**Dose:** IV amisulpride(5 mg) at induction of general anesthesia + ondansetron or dexamethasone combination vs. placebo group

**Results:**

**Incidence of Efficacy Variables in 24-h Postoperative Period**

| Complete Response Rate | Amisulpride + Standard Antiemetic (N = 572) | Placebo + Standard Antiemetic (N = 575) | P Value |
|---|---|---|---|
| All patients | 330/572 **(57.7%)** | 268/575 **(46.6%)** | <0.001 |
| 3 risk factors | 202/321 (62.9%) | 177/326 (54.3%) | 0.013 |
| 4 risk factors | 127/250 (50.8%) | 91/248 (36.7%) | <0.001 |
| Rescue medication | 234 (40.9%) (95% CI, 36.9–44.9%) | 284 (49.4%) (95% CI, 45.3–53.5%) | 0.002 |

## Conclusions:

Amisulpride can be given at induction of anesthesia in combination with a standard antiemetic significantly reduced the incidence of PONV. It is well tolerated and similar to placebo in respect of overall safety profile. The relative risk reduction of PONV is about 19–22%.[11]

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## Description:

Amisulpride is a selective dopamine-2 ($D_2$) and dopamine-3 ($D_3$) receptor antagonist, used for Prophylaxis and treatment for nausea and vomiting that may occur after surgery.

## Indication:

Amisulpride Injection is indicated in adults for:

- **Prevention of PONV:** Either alone or in combination with an antiemetic of a different class
- **Treatment of PONV:** In patients who have received antiemetic prophylaxis with an agent of a differ ent class or have not received prophylaxis.

## Mechanism Of Action:

- 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 receptors in the area postrema also play a role in emesis.

## Dosage and Administration:

- **Prevention of PONV:** Either alone or in combination with another antiemetic: 5 mg as a single intravenous dose infused over 1 to 2 minutes at the time of induction of anaesthesia.

- **Treatment of PONV:** 10 mg as a single intravenous dose infused over 1 to 2 minutes in the event of nausea and/or vomiting after a surgical procedure.

## Preparation and Administration:

- Dilution of Amisulpride Injection is not required before administration
- Amisulpride Injection is chemically and physically compatible with Water for Injection, 5% Dextrose Injection, 0.9% Sodium Chloride Injection, and Lactated Ringer's Solution (also known as Ringer's Lactate Solution, Compound Sodium Lactate Solution, and Hartmann's Solution).
- Any of which may be used to flush an intravenous line before or after administration of Amisulpride Injection.

## Advantages:

- Amisulpride, as a selective D2/D3 receptor antagonist, offers a pharmacological treatment option from a different class than commonly used prophylaxis agents, enabling guideline-driven care
- Adding amisulpride can reduce relative risk of PONV by 19-22% (In the presence of 3-4 risk factors)
- Clear solution and easy to infuse in 1 to 2 mins
- Compatible with dextrose, NaCl, WFI
- Easy to add on to existing PONV management options
- Works well both in adults and in elderly population
- Superior side effect profile
- Devoid of any major limitation

## Presentation: Supplied as 5 mg/2 mL (2.5 mg/mL) in a single-dose vial

**References**


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