Barhemsys® (amisulpride) injection 2.5 mg/mL

Treat Breakthrough PONV Promptly and Aggressively With Barhemsys

Barhemsys 10 mg for rescue treatment[1,2]

1 Barhemsys 10 mg vial
(1 x 10 mg/4 mL)

OR

2 Barhemsys 5 mg vials
(2 x 5 mg/2 mL)

Vials shown are not actual size.

Ready-to-use PONV therapy

- Administered as a 10 mg single IV dose infused (IV push) over 1 to 2 minutes[1]
- Compatible to flush IV lines before and after Barhemsys with[1]

- **Water for Injection**
- **5% Dextrose Injection**
- **0.9% Sodium Chloride Injection**
- **Lactated Ringer's Solution***

A single dose of Barhemsys 10 mg demonstrated efficacy in patients who failed prophylaxis[1,2]

Patients With Complete Response	Barhemsys (n=230)	Placebo (n=235)
At 24 hours[1,2,†] (primary endpoint)	**42%**	**29%**
At 2 hours[2,‡] (secondary endpoint)	70%	49%

Barhemsys 10 mg has an established safety profile in PONV treatment[1,§]

	Barhemsys (n=418)	Placebo (n=416)
Infusion Site Pain	6%	4%

Barhemsys is nonsedating[1,3]

Based on a post-hoc analysis of safety data from the clinical development program, 922 subjects could be evaluated for treatment-related sedation and none of them experienced sedation or sedation-like events.

Indication

Barhemsys is a selective dopamine-2 (D_2) and dopamine-3 (D_3) receptor antagonist indicated in adults for treatment of PONV in patients who have received antiemetic prophylaxis with an agent of a different class or have not received prophylaxis.

Important Safety Information

Contraindication

Barhemsys is contraindicated in patients with known hypersensitivity to amisulpride.

Click to watch video

Learn more about Barhemsys. Receive additional dosing and administration information and Important Safety Information.

Please see additional Important Safety Information on the next page.

Important Safety Information (cont.)

QT Prolongation

Barhemsys causes dose- and concentration-dependent prolongation of the QT interval. The recommended dosage is 10 mg as a single intravenous (IV) dose infused over 1 to 2 minutes.

Avoid Barhemsys in patients with congenital long QT syndrome and in patients taking droperidol.

Electrocardiogram (ECG) monitoring is recommended in patients with pre-existing arrhythmias/cardiac conduction disorders, electrolyte abnormalities (e.g., hypokalemia or hypomagnesemia), congestive heart failure, and in patients taking other medicinal products (e.g., ondansetron) or with other medical conditions known to prolong the QT interval.

Adverse Reactions

The most common adverse reaction, reported in ≥ 2% of adult patients who received Barhemsys 10 mg (N=418) and at a higher rate than placebo (N=416), in clinical trials for the treatment of PONV was infusion site pain (6% vs. 4%).

Use in Specific Populations

Pregnancy

Available data with amisulpride use in pregnant women are insufficient to establish a drug associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes.

Lactation

Amisulpride is present in human milk. There are no reports of adverse effects on the breastfed child and no information on the effects of amisulpride on milk production.

Barhemsys may result in an increase in serum prolactin levels, which may lead to a reversible increase in maternal milk production. In a clinical trial, serum prolactin concentrations in females (n=112) increased from a mean of 10 ng/mL at baseline to 32 ng/mL after Barhemsys treatment and from 10 ng/mL to 19 ng/mL in males (n=61).

No clinical consequences due to elevated prolactin levels were reported.

To minimize exposure to a breastfed infant, lactating women may consider interrupting breastfeeding and pumping and discarding breast milk for 48 hours after receiving a dose of Barhemsys.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

No overall differences in safety or effectiveness were observed between these patients and younger patients, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Drug Interactions

- Barhemsys causes dose- and concentration-dependent QT prolongation. To avoid potential additive effects, avoid use of Barhemsys in patients taking droperidol.
- ECG monitoring is recommended in patients taking other drugs known to prolong the QT interval (e.g., ondansetron).
- Reciprocal antagonism of effects occurs between dopamine agonists (e.g., levodopa) and Barhemsys. Avoid using levodopa with Barhemsys.

To report SUSPECTED ADVERSE REACTIONS, contact Acacia Pharma at 1-877-357-9237 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see full Prescribing Information.

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*Also known as Ringer's Lactate Solution, Compound Sodium Lactate Solution, and Hartmann's Solution.

†Barhemsys was evaluated as rescue treatment of PONV in a randomized, double-blind, multicenter trial in adult patients who had undergone elective ambulatory or inpatient surgery, under general anesthesia, and failed prior antiemetic prophylaxis. The primary efficacy endpoint was complete response defined as absence of any episode of emesis (vomiting or retching) or use of rescue medication within the first 24 hours after treatment, excluding emesis in the first 30 minutes. Barhemsys 5 mg is not approved for the treatment or rescue treatment of PONV.

‡The secondary endpoint was prespecified. This endpoint was not adequately powered nor error controlled and observed treatment differences cannot be regarded as statistically significant.

§Reported in ≥ 2% of patients treated with Barhemsys and at a higher rate than placebo.

FDA=Food and Drug Administration. IV=intravenous. PONV=postoperative nausea and vomiting.

1. Barhemsys [Prescribing Information], Indianapolis, IN. Acacia Pharma; 2022. **2.** Habib AS, et al. *Anesthesiology*. 2019;130(2):203-212. **3.** Acacia Pharma. Data on File.

EAGLE PHARMACEUTICALS

To learn more, visit Barhemsys.com