Barhemsys (amisulpride) injection 2.5mg/mL

BARHEMSYS®: The First and Only Antiemetic Proven for Rescue Treatment of Postoperative Nausea and Vomiting Despite Prophylaxis

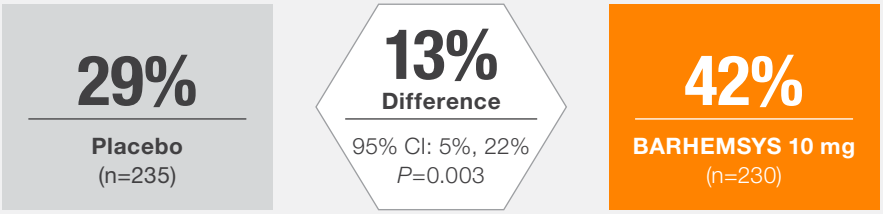
Approved by the US Food and Drug Administration (FDA) on February 26, 2020.

- PONV occurs commonly in surgical patients despite widespread prophylactic antiemetic use[1]
- Multiple pathways and receptors play a role in PONV, requiring a multimodal treatment approach[2,3]

BARHEMSYS 10 mg FOR RESCUE TREATMENT

- BARHEMSYS is a **selective dopamine-2 and dopamine-3 receptor antagonist,** offering a pharmacological option from a different class than agents commonly used for prophylaxis, **enabling guideline-driven care for PONV**[3,4]

Patients With Complete Response Within 24 Hours[4,5,*]



– **At 2 hours**, 70% and 49% of patients treated with BARHEMSYS 10 mg and placebo, respectively, met the criteria for complete response (secondary endpoint)[5]

- The **most common adverse reaction** reported for BARHEMSYS 10 mg (N=418) and at a higher rate than placebo (N=416) was **infusion site pain** (6% vs 4%)[4,†]

Indications

BARHEMSYS is a selective dopamine-2 (D_2) and dopamine-3 (D_3) receptor antagonist indicated in adults for:

- prevention of postoperative nausea and vomiting (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 different class or have not received prophylaxis

Select Important Safety Information

Contraindication

BARHEMSYS is contraindicated in patients with known hypersensitivity to amisulpride.

*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.**
†Reported in ≥2% of adult patients treated with BARHEMSYS 10 mg and at a higher rate than placebo from the PONV treatment and rescue treatment trials.

PONV=postoperative nausea and vomiting.

For additional information regarding BARHEMSYS, please contact your Hospital Territory Manager, visit **BARHEMSYS.com**, or call **1-800-281-3470**.

Please see Important Safety Information on next page and full Prescribing Information.

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QT Prolongation

BARHEMSYS causes dose- and concentration-dependent prolongation of the QT interval. The recommended dosage is 5 mg or 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

Common adverse reactions reported in ≥ 2% of adult patients who received BARHEMSYS 5 mg (N=748) and at a higher rate than placebo (N=741) in clinical trials for the prevention of PONV were: chills (4% vs. 3%), hypokalemia (4% vs. 2%), procedural hypotension (3% vs. 2%), and abdominal distention (2% vs. 1%).

Serum prolactin concentrations were measured in one prophylaxis study where 5% (9/176) of BARHEMSYS-treated patients had increased blood prolactin reported as an adverse reaction compared with 1% (1/166) of placebo-treated patients.

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

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.

Renal Impairment

Avoid BARHEMSYS in patients with severe renal impairment (estimated glomerular filtration rate [eGFR] < 30 mL/min/1.73 m^2). The pharmacokinetics of amisulpride in patients with severe renal impairment have not been adequately studied in clinical trials. Amisulpride is known to be substantially excreted by the kidneys, and patients with severe renal impairment may have increased systemic exposure and an increased risk of adverse reactions.

No dosage adjustment is necessary in patients with mild to moderate renal impairment (eGFR ≥ 30 mL/min/1.73 m^2).

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.

Please see full Prescribing Information.

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References: 1. White PF, et al. *Anesth Analg.* 2008;107(2):452-458. **2.** Kovac AL, et al. *Postoperative Nausea and Vomiting: A Practical Guide*. Cambridge, UK: Cambridge University Press; 2016:13-22. **3.** Gan TJ, et al. *Anesth Analg*. 2020;131(2):411-448. **4.** BARHEMSYS [package insert]. Indianapolis, IN: Acacia Pharma Inc; 2020. **5.** Habib AS, et al. *Anesthesiology.* 2019;130:203-212.

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