Barhemsys (amisulpride) injection 2.5 mg/mL

Barhemsys®: Reimbursement and Ordering Information

Barhemsys 10 mg is the first and only FDA-approved rescue treatment for PONV after failed prophylaxis.[1]

J-code for billing: J0184
effective January 1, 2024

Granted 3-year transitional pass-through payment status
effective October 1, 2023

- **Provides a treatment option from a different drug class than agents commonly used in prophylaxis[1-3]**
- **Proven efficacy in treating breakthrough PONV despite prophylaxis[1,3]**
- **Nonsedating[1,4,*]**
- **Established safety profile[1,†]**
- **35 minutes shorter mean PACU LOS and 6 hours shorter mean hospital LOS compared to placebo[3,‡]**

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 Information

Reimbursement[5]	**Medicare Reimbursement for HOPDs and ASCs:** ASP + 6% **Commercial Reimbursement:** Barhemsys may be reimbursed as a percentage of billed charges§ Note: Reimbursement is subject to CMS updates.
NDC[1]	**Barhemsys 5 mg** · 71390-125-20 (bundle of 10 vials) · 71390-125-21 (1 vial) **Barhemsys 10 mg** · 71390-125-50 (bundle of 10 vials) · 71390-125-51 (1 vial) Note: Individual vial ordering is not available.
Dosage Form[1]	Injection: 5 mg/2 mL (2.5 mg/mL) or 10 mg/4 mL (2.5 mg/mL) as a clear, colorless sterile solution in a single-dose vial
Real-Time Stability[4]	60-month room temperature shelf life when protected from light
Handling Requirements[1]	· No refrigeration is needed · No reconstitution is required · Protect from light; Barhemsys is subject to photodegradation; administer Barhemsys within 12 hours of removal of vial from the protective carton
Packaging Specifications[4]	· Individual carton size: 29.5 mm × 29.5 mm × 76.5 mm · Package size: 10 cartons, shrink-wrapped

Dosing and Administration[1]

Recommended Adult Dosage Regimen

Administered as a single IV dose infused (IV push) over 1 to 2 minutes

PONV Rescue Treatment
10 mg
WAC: $90.00

1 Barhemsys 10 mg vial
(1 x 10 mg/4 mL)
Corresponds to 10 billable units

PONV Prevention
5 mg
WAC: $45.00

1 Barhemsys 5 mg vial
(1 x 5 mg/2 mL)
Corresponds to 5 billable units

Vials shown are not actual size.

ASC=ambulatory surgical center. ASP=average sales price. HOPD=hospital outpatient department. IV=intravenous. LOS=length of stay. NDC=National Drug Code. PACU=postanesthesia care unit. PONV=postoperative nausea and vomiting. WAC=wholesale acquisition cost.

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

Wholesale Information

	Barhemsys 10 mg Item Number	Barhemsys 5 mg Item Number	Contact Phone	Order Portal or Email
AmerisourceBergen	10257113	10238345	844-222-2273	abcorder.amerisourcebergen.com
Besse Medical	10257135	58113	800-543-2111	besse.com/contact-us
Cardinal Health	5716188	5666474	800-926-3161	orderexpress.cardinalhealth.com
Curascript	430870	414794	877-599-7748	customer.service@curascript.com
Henry Schein	1401706	1400931	800-772-4346	henryschein.com/medical
McKesson	2314854	1563477	855-625-6285	connect.mckesson.com
McKesson Medical-Surgical	1189779	1173714	855-571-2100	mms.mckesson.com
Morris & Dickson Co., LLC	058040	908160	800-388-3833	mdwebportal.net

For additional information regarding Barhemsys, please contact your Key Account Manager or visit **Barhemsys.com**.
For reimbursement questions, please contact: **Barhemsys.reimbursement@eagleus.com**.

Indications

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- prevention of postoperative nausea and vomiting (PONV), either alone or in combination with an antiemetic of a different class
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Important Safety Information

Contraindication

Barhemsys is contraindicated in patients with known hypersensitivity to amisulpride.

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

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**.
BAR HCP ISI 09/2022

*Based on data from the PONV clinical trial program, treatment-related sedation or sedation-like reactions were not reported in 922 patients who received 5-40 mg amisulpride.
†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%).
‡In the phase III trial of rescue treatment of PONV after failed prophylaxis, patients in the Barhemsys 10 mg group had 35 minutes shorter mean PACU length of stay and 6 hours shorter hospital length of stay than patients in the placebo group. The secondary endpoints listed were prespecified. These endpoints were not adequately powered nor error controlled, and observed treatment differences cannot be regarded as statistically significant.
§Commercial payers may reimburse for Barhemsys as part of the surgical supply package across all sites of care or as a percentage of billed charges. Reach out to payers to confirm coverage details.

1. Barhemsys [package insert]. Indianapolis, IN: Acacia Pharma Inc; 2022. **2.** Gan TJ, et al. *Anesth Analg.* 2020;131(2):411-448. **3.** Habib AS, et al. *Anesthesiology.* 2019;130(2):203-212. **4.** Acacia Pharma. Data on File. **5.** Centers for Medicare & Medicaid Services. Addendum B Updates. CMS website. Published October 2023. Accessed November 30, 2023. https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/addendum-b-updates/october-2023-0.

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