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Acacia Pharma Invites You to Attend an Educational Program to Discuss an Antiemetic for PONV

Barhemsys[®]: The First and Only Antiemetic Approved for Rescue Treatment of Postoperative Nausea and Vomiting (PONV) Despite Prophylaxis

Do your ERAS protocols address breakthrough postoperative nausea and vomiting (PONV)?

PONV is a common complication of surgery and anesthesia.¹ In fact, over 30% of your high-risk patients may still experience PONV despite antiemetic prophylaxis.^{2,3} PONV persists as one of the major causes of patient dissatisfaction following anesthesia, even more concerning than pain.⁴⁻⁶ Among patients who have PONV—including those in the rescue setting—nausea (>95%) is far more common than vomiting (>20%).^{2,7} Nausea also has an impact on the length of stay after ambulatory anesthesia. Patients with nauseamay stay an average of 1.4 hours longer than patients without nausea.⁸ Join us to learn more about a proven antiemetic for PONV rescue that may help you reach your goals for enhanced recovery.^{2,9}

Learning Objectives

- · Understand the incidence and risk factors associated with nausea and vomiting in a surgical setting
- · Recognize the burden and consequences of PONV
- · Identify unmet needs in the management of PONV
- · Gain knowledge on the safety and efficacy of Barhemsys as a rescue treatment for PONV in adult patients

DATE/TIME

Thursday, May 05, 2022 6:00 PM Eastern

LOCATION Craftsman Inn 7300 E. Genesee Street Fayetteville, New York 13066

SPEAKER

Erik Rauch, CRNA, DNP, NSPM-C, DAAPM Assistant Professor, Nurse Anesthesia Program University of South Florida College of Nursing Tampa, Florida Regional Director for Advanced Practice Providers, Chief CRNA, Envision Physician Services Bayfront Health St. Petersburg St. Petersburg, Florida

In accordance with internal and industry requirements, Acacia Pharma and its representatives may not pay for or provide alcohol at a Speaker Program. Additionally, repeat attendance at a Speaker Program on the same or substantially same topic is generally not appropriate.

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Indications

Barhemsys is a selective dopamine-2 (D₂) and dopamine-3 (D₃) 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 notreceived prophylaxis

Select Important Safety Information

Contraindication

Barhemsys is contraindicated in patients with known hypersensitivity to amisulpride.

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



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QT Prolongation

Barhemsys causes dose- and concentrationdependent prolongation of the QT interval. The recommended dosage is5 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 $\ge 2\%$ 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 Barhemsystreated 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 $\ge 2\%$ 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%).

Please see full <u>Prescribing Information</u>.

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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 mayconsider 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 m²). 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 mayhave increased systemic exposure and an increased risk of adverse reactions.

No dosage adjustment is necessary in patients with mild to moderate renal impairment (eGFR \geq 30 mL/min/1.73 m²).

Drug Interactions

- Barhemsys causes dose- and concentrationdependent QTprolongation. 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 levodopawith Barhemsys

1. Gan TJ, et al. Anesth Analg. 2020;131(2):411-448. 2. Habib AS, et al. Anesthesiology. 2019;130(2):203-212. 3. White PF, et al. Anesth Analg. 2008;107(2):452-458. 4. Macario A, et al. Anesth Analg. 1999;89(3):652-658. 5. Okuda C, et al. Braz J Anesthesiol. 2021;71(2):103-109. 6. Eberhart LH, et al. Br J Anaesth. 2002;89(5):760-761. 7. Habib AS, et al. Curr Med Res Opin. 2006;22(6):1039-1099. 8. Green G, et al. Acta Anaesthesiol Scand. 1993;37(8):742-746. 9. Barhemsys [package insert]. Indianapolis, IN: Acacia Pharma Inc.

