BYFAVO Now Approved by US FDA www.Byfavo.com

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BYFAVO™

(remimazolam) for injection

Very Rapid Onset/Offset Procedural Sedative with Favorable Safety Profile

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Summary

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- BARHEMSYS® was approved in late February for PONV
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COVID-19 Impact on launch plans

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Procedural Sedation Market Opportunity

>40 million

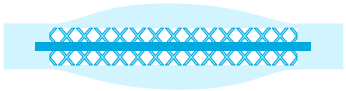
procedures each year requiring sedation

~25 million

GI procedures performed each year

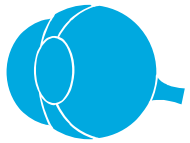
>80%

have sedation administered by an anesthesia provider



>6 million

Interventional Radiology



~4 million

Ophthalmic Procedures

~1 million

Bronchoscopy

~1.5 million

Cosmetic/ Plastic Surgery

Total addressable market in procedural sedation = >$1B/year

Based on selling price of $25-35 per dose

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BYFAVO Addresses Unmet Need in Procedural Sedation

Propofol

fast acting but significant safety issues

- Rapid onset and offset anesthetic with narrow therapeutic index
- **Dose-related cardiorespiratory depression**, pain at injection site
- Non-linear dosing effects due to individual variability
- **Needs continuous monitoring by anesthesiologist, no reversal agent**
- Lipid formulation susceptible to bacterial contamination

Midazolam

better safety profile but longer onset and recovery

- Benzodiazepine sedative, reversible by flumazenil
- **Slower onset and offset**
- Metabolized by cytochrome system; individual variability affects sedation
- Active metabolite can accumulate and cause prolonged sedation
- **Risk of respiratory depression**

BYFAVO

fast acting AND favorable safety profile

- **Rapid onset/offset** benzodiazepine
- Rapid biotransformation into inactive metabolites via non-specific tissue esterases – not dependent on liver enzymes
- **Predictable behavior, no drug interactions**
- **Reliable sedation, reliable safety profile**
- Reversible by flumazenil

Sources: Colao J, *et al. J. Anesth. Clin. Res.* 2016; 7:690; Whizar-Lugo V, *et al. J. Anesth. Crit. Care.* 2016; 4(6): 00166.

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Product Labelling

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use BYFAVO safely and effectively. See full prescribing information for BYFAVO.

BYFAVO™ (remimazolam) for injection, for intravenous use,
Scheduling pending
Initial U.S. Approval: 2020

WARNING: PERSONNEL AND EQUIPMENT FOR MONITORING AND RESUSCITATION, AND RISKS FROM CONCOMITANT USE WITH OPIOID ANALGESICS AND OTHER SEDATIVE-HYPNOTICS

See full prescribing information for complete boxed warning

- Only personnel trained in the administration of procedural sedation, and not involved in the conduct of the diagnostic or therapeutic procedure, should administer BYFAVO. (2.1, 5.1)
- Administering personnel must be trained in the detection and management of airway obstruction, hypoventilation, and apnea, including the maintenance of a patent airway, supportive ventilation, and cardiovascular resuscitation. (2.1, 5.1)
- BYFAVO has been associated with hypoxia, bradycardia, and hypotension. Continuously monitor vital signs during sedation and through the recovery period. (2.1, 5.1)
- Resuscitative drugs, and age-and size-appropriate equipment for bag/valve/mask assisted ventilation must be immediately available during administration of BYFAVO. (2.1, 5.1)
- Concomitant use of benzodiazepines with opioid analgesics may result in profound sedation, respiratory depression, coma, and death. The sedative effect of intravenous BYFAVO can be accentuated by concomitantly administered CNS depressant medications, including other benzodiazepines and propofol. Continuously monitor patients for respiratory depression and depth of sedation. (5.2, 7.1)

INDICATIONS AND USAGE

BYFAVO (remimazolam) for injection is a benzodiazepine indicated for the induction and maintenance of procedural sedation in adults undergoing procedures lasting 30 minutes or less. (1)

DOSAGE AND ADMINISTRATION

Individualize and titrate BYFAVO dosing to desired clinical effect. (2.2)

Adult Patients:

- Administer an initial dose intravenously as a 5 mg push injection

Debilitated Patients (ASA III-IV, at the discretion of the physician):

- Based on the general condition of the patient, administer 2.5 mg to 5 mg over 1-minute time period. (2.2)
- If necessary, administer supplemental doses of 1.25 mg to 2.5 mg intravenously over a 15-second time period. At least 2 minutes must elapse prior to the administration of any supplemental dose. (2.2)

DOSAGE FORMS AND STRENGTHS

Each glass, single-patient-use vial contains 20 mg BYFAVO (remimazolam) lyophilized powder for reconstitution, equivalent to 27.2 mg remimazolam besylate. (3)

CONTRAINDICATIONS

Hypersensitivity to dextran 40. (4)

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions: Hypersensitivity reactions including anaphylaxis may occur. (5.3)
Neonatal Sedation: Benzodiazepine use during pregnancy can result in neonatal sedation. Observe newborns for signs of sedation and manage accordingly. (5.4)
Pediatric Neurotoxicity: In developing animals, exposures greater than 3 hours cause neurotoxicity. Weigh benefits against potential risks when considering elective procedures in children under 3 years old. (5.5)

ADVERSE REACTIONS

The most common adverse reactions (>10%) in patients receiving BYFAVO for procedural sedation are hypotension, hypertension, diastolic hypertension, systolic hypertension, hypoxia, and diastolic hypotension. (6)

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

USE IN SPECIFIC POPULATIONS

Lactation: A lactating woman may pump and discard breast milk for 5 hours after treatment with BYFAVO. (8.2)
Pediatric Use: BYFAVO should not be used in patients less than 18 years of age. (8.4)
Geriatric Use: Sedating drugs, such as BYFAVO, may cause confusion and over-sedation in the elderly; elderly patients generally should be observed closely. (8.5)
Severe Hepatic Impairment: In patients with severe hepatic impairment the dose of BYFAVO should be carefully titrated to effect. Depending on the overall status of the patient, reduced doses might be indicated

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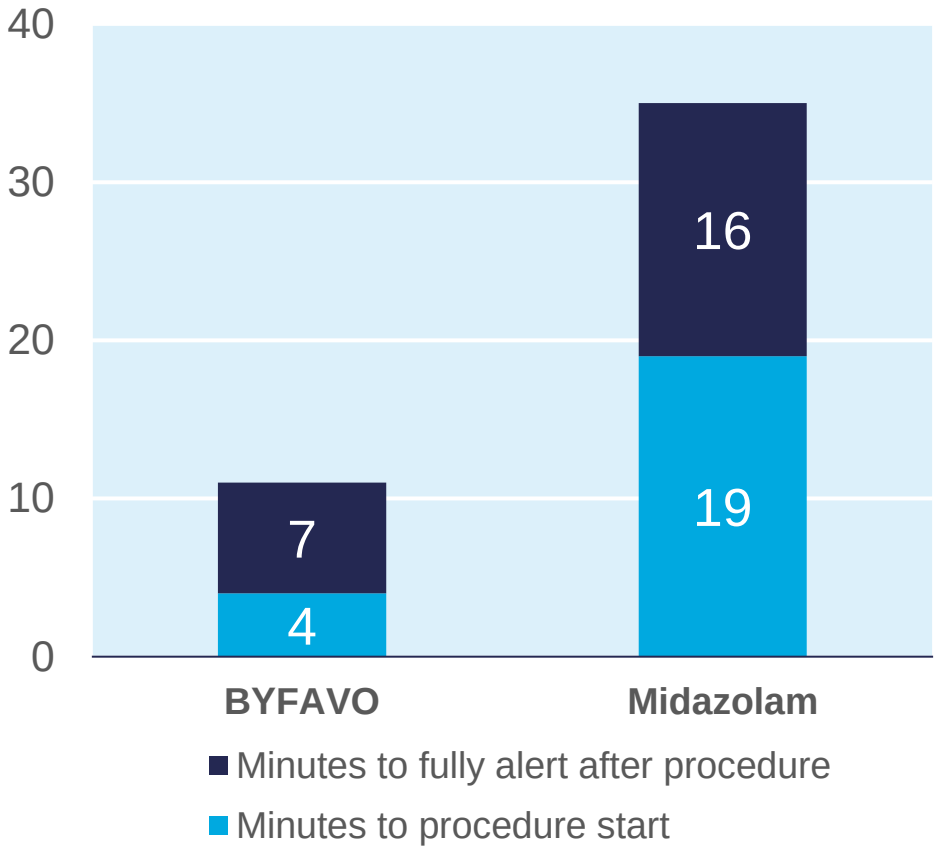
Very Rapid Onset/Offset with a Favorable Safety Profile

Average Procedure Timings



Key Adverse Events

	BYFAVO	Midazolam
Any adverse event	**74%**	**91%**
Vascular disorders	62%	81%
Cardiac disorders	18%	26%
Respiratory disorders	4%	6%

Source: Rex DK *et al. Gastrointest. Endosc.* 2018 Sep;88(3):427-437.

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BYFAVO™ – Compelling Clinical Proposition

Approved with a broad label

- Indicated for **procedural sedation in adults** in procedures lasting 30 mins or less
- Substantial clinical data package shows **compelling efficacy and safety** in colonoscopies and bronchoscopies, including least fit patients

Throughput and health economic benefits

- **Very rapid onset/offset enables shorter procedure times and greater patient throughput for hospitals and surgical centers**

Commercial synergy with BARHEMSYS

- Target prescribers: **anesthesiologists and proceduralists in hospitals and ambulatory surgery centers**

Helps post-COVID pressure to alleviate procedural backlog

- **Shorter procedure times allow increased procedural volumes**
- Both midazolam and propofol currently on FDA drug shortages list

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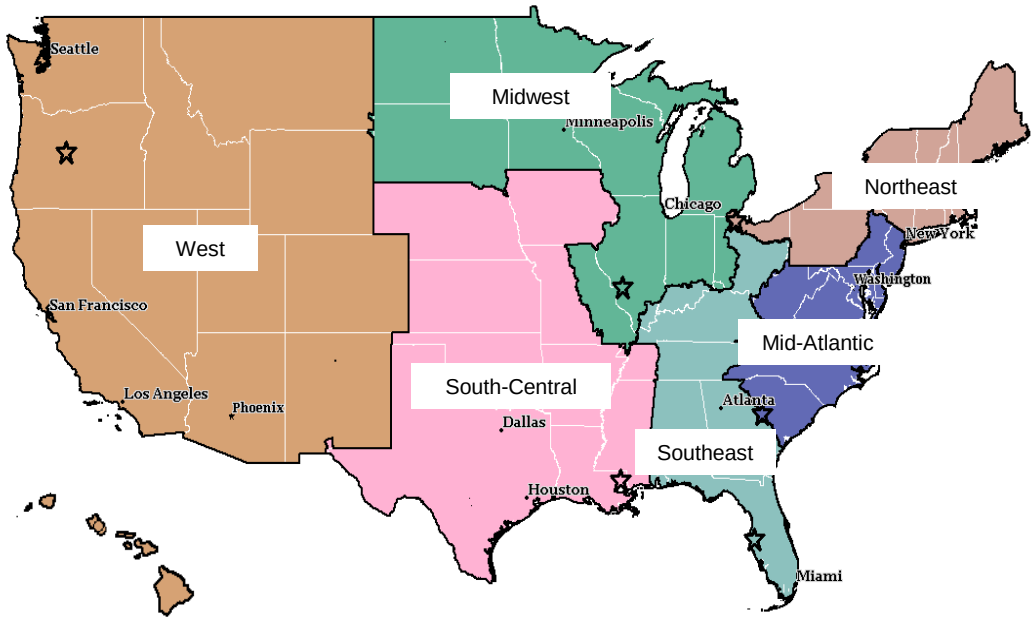
Highly Experienced Commercial Team with Proven Hospital Success



Team has direct experience successfully launching OFIRMEV into same market to same key customers

Field Force Design

- 1 VP of Sales
- 1 National Accounts Group Leader
- 1 National MSL Group Leader
- 6 Sales Regions each with:
  - 1 RBD
  - 1 MSL
  - 1 National Account Director
  - 5 Hospital Territory Managers

Commercial Leadership Team

28+	60+
Years avg industry	Launches

Sales Leadership Team

22	18+
Years avg industry	Years hospital

National Accounts Team

24	21+
Years avg industry	Years hospital

Medical Science Liaison Team

22	10+
Years avg industry	Years as MSL

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COVID-19 Situation and Impact

> “The OR accounts for up to 65% of hospital profit margin, so this missing volume is cutting deeply into cash flow and net income.”
>
> – Becker’s Hospital Review

COVID-19 impact on hospitals and surgical centers

- Non-essential surgeries cancelled creating a significant backlog
- Physical access to hospital decision-makers even more restricted

Hospitals profits have suffered and need to be restored quickly

- Surgeries and procedures are major contributors to hospital profits
- Providers need to dramatically increase throughput to regain lost profits

Our products and team are ideally positioned to help

- BARHEMSYS and BYFAVO can help improve patient throughput – both now even more relevant and of greater interest to customers
- Our strong relationships will help us gain access to key decision-makers

How to rebuild surgical revenue after COVID-19, **Becker’s Hospital Review**, accessed via https://www.beckershospitalreview.com/strategy/how-to-rebuild-surgical-revenue-after-covid-19-even-if-you-just-lost-60-of-your-or-volume.html

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