ZUNVEYL®
(benzgalantamine)

A clear choice for Alzheimer's disease

With proven medication + purposefully designed delivery, ZUNVEYL can help address treatment challenges of Alzheimer's disease in older adults.

INDICATION AND USAGE

ZUNVEYL is a cholinesterase inhibitor indicated for the treatment of mild to moderate dementia of the Alzheimer's type in adults.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

ZUNVEYL is contraindicated in patients with known hypersensitivity to benzgalantamine, galantamine, or to any inactive ingredients in ZUNVEYL. Serious skin reactions have occurred.

Please see additional Important Safety Information throughout and full Prescribing Information from your representative.

ZUNVEYL
(benzgalantamine)
DELAYED RELEASE TABLETS
5 mg | 10 mg | 15 mg

US-ZUNV-00005 V3

Treating Alzheimer's Disease (AD) is Challenging

Symptom management can be complex

UP TO 80% of patients with AD suffer from a wide range of behavioral symptoms such as agitation, sleep disturbances, wandering, apathy, anxiety, and aberrant motor behavior.[1,2]

UP TO 64% of patients with AD experience sleep disturbances, which can exacerbate cognitive decline and behavioral issues.[3-7]

According to long-term care (LTC) staff, side effects from current AD medications, including GI discomfort and insomnia, may lead to:[10]

- **Disruption in mealtimes**
- **Inability to participate in social activities**
- **Risk of falls**

Persistent treatment can be an issue

UP TO 47% of patients with AD commonly reported gastrointestinal (GI) adverse effects with current acetylcholinesterase inhibitors (AChEIs), including nausea (11%-47%), vomiting (10%-31%), diarrhea (5%-19%), and anorexia (4%-17%).[8]

73% of patients with AD discontinue treatment within 18 weeks due to side effects, including GI discomfort and sleep disturbances.[9]

Residents with AD Present with Varying Profiles

Residents living with AD can differ in cognitive status, symptom burden, comorbidities, and treatment experience

Ruth*

Discontinued Treatment Due to Tolerability Issues

- Tested cognitively impaired on the Brief Interview for Mental Status (BIMS)
- Previously treated with an AChEI for Alzheimer’s disease, but discontinued due to gastrointestinal adverse effects
- Demonstrating decline in basic activities of daily living (ADLs), requiring assistance
- Takes medications for multiple comorbidities, including proton pump inhibitor for gastroesophageal reflux disease (GERD) and beta blocker for hypertension

George*

Suffers from Insomnia

- Diagnosed with dementia
- Currently treated with an AChEI for Alzheimer's disease
- Experienced nighttime fall while wandering
- Takes a hypnotic agent to manage insomnia

Eleanore*

Experiences Persistent Behavioral Symptoms

- Demonstrating progressive cognitive decline
- On low dose AChEI for Alzheimer’s disease, but insufficient efficacy observed
- Needs assistance with basic ADLs, but resistant and sometimes combative to staff assistance
- Currently takes an atypical antipsychotic to manage agitation

* Not an actual resident with AD.

ZUNVEYL: Purposefully Designed Delivery

- **ZUNVEYL is the first and only FDA-approved AChEI to utilize prodrug enteric-coated, delayed-release technology to minimize absorption in the stomach and overstimulation of neurons in the gastrointestinal (GI) nervous system[11,12]**

Enteric-Coated

ZUNVEYL passes through the stomach inertly, limiting absorption[12]

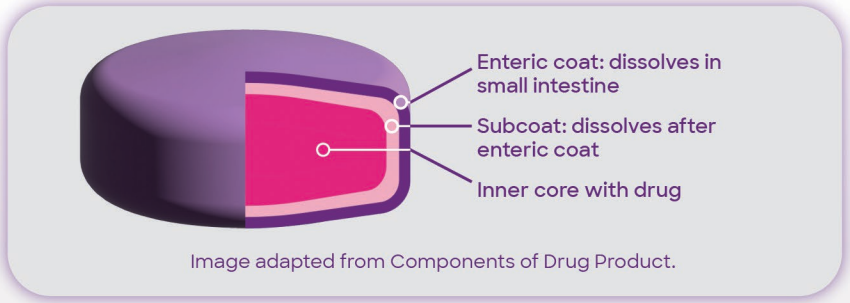


Image adapted from Components of Drug Product.

Prodrug Design

ZUNVEYL remains inactive until after first pass metabolism in the liver, and then converts to active galantamine[11-13]

Primary conversion of ZUNVEYL to galantamine occurs in the liver

ZUNVEYL provides dual protection

- Protects from peripheral and central cholinergic side effects[12]
  - Minimizes stomach absorption, enabling targeted delivery to the intestine
  - May minimize central emetic activation

FDA=U.S. Food and Drug Administration.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS

Serious Skin Reactions: Serious skin reactions (Stevens-Johnson syndrome and acute generalized exanthematous pustulosis) have been reported in patients receiving galantamine (the active metabolite of ZUNVEYL tablets). If signs or symptoms suggest a serious skin reaction, use of this drug should not be resumed, and alternative therapy should be considered.

Anesthesia: See Drug Interactions Section.

ZUNVEYL (benzgalantamine) DELAYED RELEASE TABLETS 5 mg | 10 mg | 15 mg

The Dual Acting Mechanism of Action of ZUNVEYL

ZUNVEYL is believed to work in two ways*

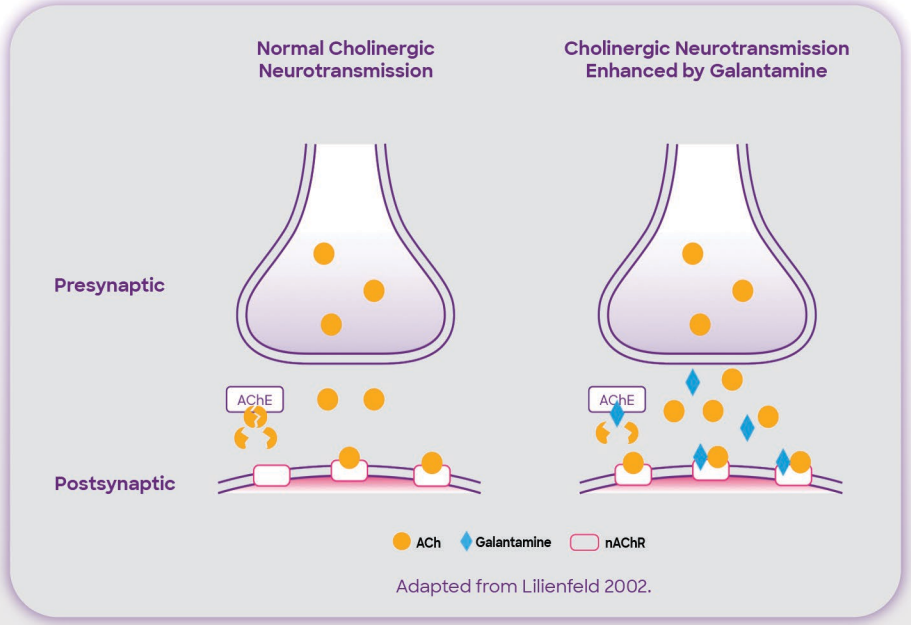
Acetylcholinesterase Inhibitor

- Inhibits acetylcholinesterase, preventing the breakdown of acetylcholine and increasing its availability[11]

Nicotinic Receptor Modulator

- Modulates nicotinic acetylcholine receptors (nAChR) making acetylcholine pathways more responsive[14,15]
  - Stimulates the cholinergic pathway
  - Decreases inflammation
  - Buffers the effects of amyloid
  - Enhances release of other transmitters: glutamate, dopamine, GABA, serotonin, and norepinephrine

GABA=gamma-aminobutyric acid.



*The mechanism of action of ZUNVEYL is not fully understood.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

Cardiovascular Conditions: Cholinesterase inhibitors, including ZUNVEYL, have vagotonic effects on the sinoatrial and atrioventricular nodes, leading to bradycardia and AV block. Bradycardia and all types of heart block have been reported in patients taking cholinesterase inhibitors, both with and without known underlying cardiac conduction abnormalities. Therefore, all patients should be considered at risk for adverse effects on cardiac conduction.

Patients treated with galantamine up to 24 mg/day using the recommended dosing schedule showed a dose-related increase in risk of syncope.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.

ZUNVEYL (benzgalantamine) DELAYED RELEASE TABLETS 5 mg | 10 mg | 15 mg

ZUNVEYL Bioequivalence Study Designs

ZUNVEYL was approved by the FDA via the 505(b)(2) regulatory pathway, based on the previously established safety and efficacy for galantamine hydrobromide[16]

- The efficacy of ZUNVEYL is based upon 3 studies demonstrating bioequivalencein healthy adults comparing galantamine immediate-release (IR) tablets and galantamine extended-release (ER) capsules with ZUNVEYL.[17-19]
  - 5 mg delayed-release tablet of ZUNVEYL was shown to be equivalent to one 4 mg tablet of galantamine hydrobromide IR
  - 5 mg delayed-release tablet of ZUNVEYL, administered twice daily, was shown to be equivalent to one 8 mg galantamine hydrobromide ER capsule administered once daily
- A dose proportionality study was conducted that confirmed ZUNVEYL exhibits linear pharmacokinetics equivalent to galantamine.[20]
- In the 4 studies above, the most common adverse events were increased alanine transaminases (n=4), diarrhea (n=2), and vomiting (n=1).[17-20]

Phase 1 Clinical Study and # of Participants	Study Design	Study Objective
STUDY-01[17] 36 Healthy Adult Participants	• Open-label, balanced, randomized, single-dose, 2-treatment, 2-period, 2-way crossover study • Participants randomly assigned to one of 2 treatment order sequences with a 7-day washout period between treatments	• **Evaluate relative bioavailability of ZUNVEYL delayed-release 5 mg tablet compared with galantamine hydrobromide (IR) 4 mg tablet under *fed conditions***
STUDY-02[18] 36 Healthy Adult Participants	• Open-label, balanced, randomized, single-dose, 2-treatment, 2-period, 2-way crossover study • Participants randomly assigned to one of 2 treatment order sequences with a 7-day washout period between treatments	• **Evaluate relative bioavailability of ZUNVEYL delayed-release 5 mg tablet compared with galantamine hydrobromide (IR) 4 mg tablet under *fasting conditions***
STUDY-03[19] 40 Healthy Adult Participants	• Open-label, balanced, randomized, multiple-dose, 2-treatment, 2-arm, 2-period comparative steady state study • Participants randomly assigned to one of 2 treatment order sequences with a 7-day washout period between treatments	• **Evaluate steady state of ZUNVEYL delayed-release tablets 5 mg (BID) compared with Razadyne ER (galantamine extended-release capsules) 8 mg (QD)**
STUDY-04[20] 42 Healthy Adult Participants	• Open-label, balanced, randomized, 3-arm, 3-treatment, single-dose parallel study • Participants randomly assigned to one of 3 treatment arms and received a single dose of the assigned investigational product	• **Evaluate the pharmacokinetics and dose proportionality of ZUNVEYL delayed-release tablets 5 mg, 10 mg, and 15 mg in healthy adult participants under fasting conditions**

BID=twice daily; FDA=U.S. Food and Drug Administration; QD=once daily.

Please see most common adverse reactions for galantamine on slide 11.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

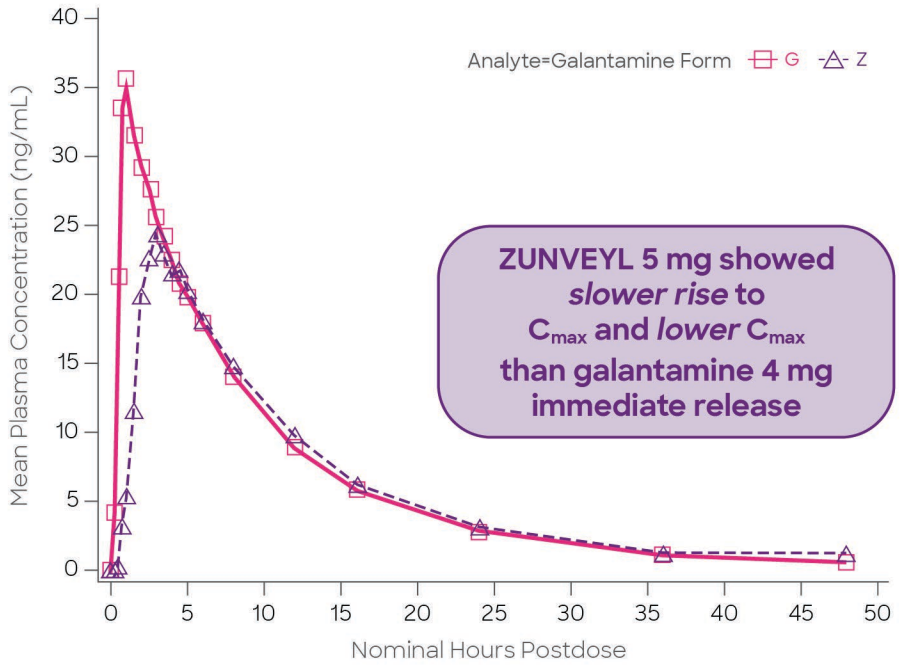
Gastrointestinal Conditions: Cholinesterase inhibitors, including ZUNVEYL, may increase gastric acid secretion. Patients should be monitored closely for active or occult gastrointestinal bleeding, especially those with a history of ulcer disease or those receiving concurrent nonsteroidal anti-inflammatory drugs (NSAIDs). Clinical studies of galantamine have shown no increase, relative to placebo, in the incidence of either peptic ulcer disease or gastrointestinal bleeding.

ZUNVEYL (benzgalantamine) DELAYED RELEASE TABLETS 5 mg | 10 mg | 15 mg

Clear Support for Pharmacokinetic Consistency

Results from the ZUNVEYL bioequivalence studies

Mean Galantamine Plasma Concentrations (ng/mL) Over Time[18]



- Reaches bioequivalence without initial peak.[18]
- Narrow confidence intervals for consistent delivery (90% CI, 88.9-95.2).[18]
- Bioequivalent at 48 hours.[18]

G=galantamine; Z=ZUNVEYL.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

Gastrointestinal Conditions (Cont'd): Galantamine has been shown to produce nausea, vomiting, diarrhea, anorexia, and weight loss. Monitor the patient's weight during therapy with ZUNVEYL.

Genitourinary Conditions: Although this was not observed in clinical trials with galantamine, cholinesterase inhibitors, including ZUNVEYL, may cause bladder outflow obstruction.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.

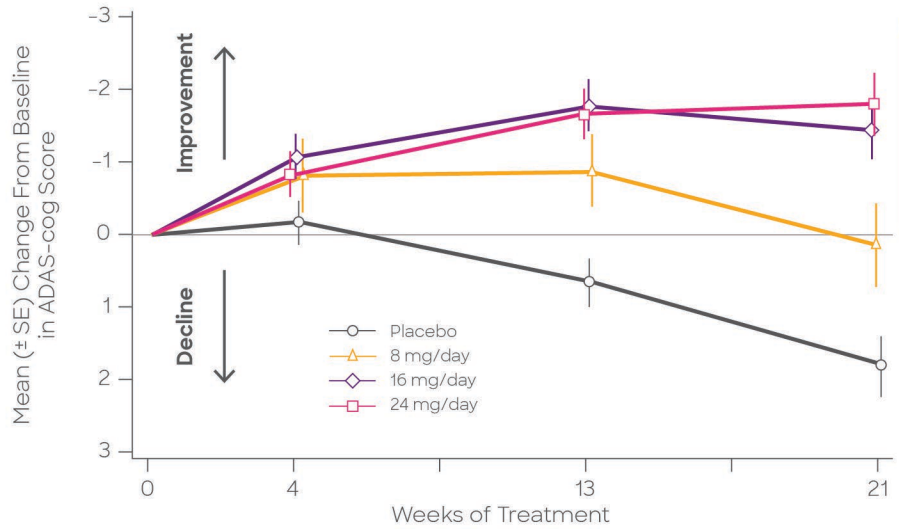
ZUNVEYL (benzgalantamine)
DELAYED RELEASE TABLETS
5 mg | 10 mg | 15 mg

Clear Improvement in Cognitive Function

In a 21-week study of 978 patients with mild to moderate Alzheimer's disease, galantamine (the active ingredient of ZUNVEYL) showed sustained cognitive benefits through ADAS-cog scores.[11,21]

Co-Primary Clinical Endpoint: ADAS-cog

Time Course of the Change From Baseline in ADAS-cog Score for Patients Completing 21 Weeks of Treatment[11]



Improved ADAS-cog scores demonstrated delayed impairment in cognitive function, including memory, orientation, attention, language, reasoning, and praxis[11]

The mean difference versus placebo in ADAS-cog change scores was 3.3 points for 16 mg/day and 3.6 points for 24 mg/day[11]

Study design: A randomized, double-blind, placebo-controlled study of galantamine immediate-release tablets. Patients were randomized to doses of 8, 16, or 24 mg of galantamine per day, or to placebo, each given in 2 divided doses. Treatment was initiated at 8 mg/day for all patients randomized to galantamine and increased by 8 mg/day every 4 weeks. There was no statistically significant difference between the 16 mg and 24 mg treatments.[11]

ADAS-cog=Alzheimer's Disease Assessment Scale-Subscale-Cognitive; SE=standard error.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

Neurological Conditions: Cholinesterase inhibitors are believed to have some potential to cause generalized convulsions. Seizure activity may also be a manifestation of Alzheimer's disease. Patients with Alzheimer's disease should be monitored closely for seizures while taking ZUNVEYL.

Pulmonary Conditions: Cholinesterase inhibitors, including ZUNVEYL, should be prescribed with care to patients with a history of severe asthma or obstructive pulmonary disease. Monitor for respiratory adverse reactions.

ZUNVEYL (benzgalantamine) DELAYED RELEASE TABLETS 5 mg | 10 mg | 15 mg

Improved Cognition, Behavior, and Daily Living

Patients treated with galantamine (the active ingredient of ZUNVEYL) showed significant gains or sustainment in CIBIC-plus scores, a measure of overall clinical response to therapy, demonstrating its impact across cognition, behavior, and daily living activities.[11]

Co-Primary Clinical Endpoint: CIBIC-plus

Mean Change from Baseline in CIBIC-plus Scores for Patients Completing 21 Weeks of Treatment[11]

Improved CIBIC-plus scores vs placebo demonstrated delayed impairment in 4 areas of patient function: general, cognitive, behavioral, and ADLs[11]

At 5 months, 64% to 68% of the 16 mg/day and 24 mg/day groups remained stable or improved compared with 47% of patients in the placebo group (observed cases analysis; $P<0.001$)[21]

- **The mean difference versus placebo in CIBIC-plus scores was 0.41 points for galantamine IR 16 mg/day and 0.44 points for galantamine IR 24 mg/day.**[11]

ADLs=activities of daily living; CIBIC-plus=Clinician's Interview-Based Impression of Change Plus caregiver input; IR=immediate release.

IMPORTANT SAFETY INFORMATION (CONT'D)

ADVERSE REACTIONS

The most common adverse reactions with galantamine tablets (≥5%) were nausea, vomiting, diarrhea, dizziness, headache, and decreased appetite.

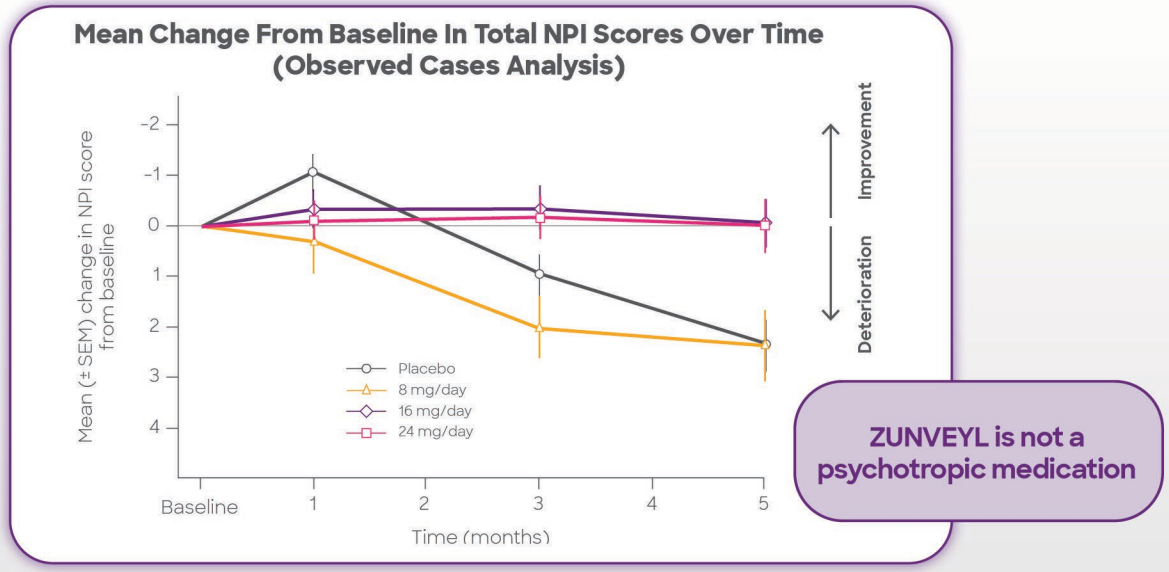
Please see additional Important Safety Information throughout and accompanying full Prescribing Information.

ZUNVEYL (benzgalantamine) DELAYED RELEASE TABLETS 5 mg | 10 mg | 15 mg

Improvement on Behavioral Symptoms

Among patients treated with therapeutic doses of galantamine (the active ingredient of ZUNVEYL), the results of the NPI indicate a significant benefit of galantamine on behavioral symptoms compared to placebo[21]

Secondary Clinical Endpoint: Neuropsychiatric Inventory (NPI)



ZUNVEYL is not a psychotropic medication

SEM=Standard Error of the Mean

At 5 months, both the 16 mg/day and 24 mg/day groups had significantly better NPI total scores than placebo (observed cases analysis; $P<0.05$)[21]

- **The NPI assesses the frequency and severity of symptoms in 10 behavioral domains[21]**

NPI BEHAVIORAL DOMAINS[22]	DEFINITIONS
DELUSIONS	False beliefs about being harmed or in danger
HALLUCINATIONS	See, hear, or experience things not present
AGITATION/AGGRESSION	Resistant to care, aggressive behavior
DEPRESSION/DYSPHORIA	Persistent feelings of sadness and hopelessness
ANXIETY	Excessive worry or fear disproportionate to situation
ELATION/EUPHORIA	Excessive cheerfulness or inappropriate humor
APATHY/INDIFFERENCE	Lack of motivation, lack of interest in surroundings
DISINHIBITION	Socially inappropriate behavior or lack of restraint
IRRITABILITY/LABILITY	Quick to anger or displaying sudden mood changes
ABERRANT MOTOR BEHAVIOR	Repetitive, purposeless movements

IMPORTANT SAFETY INFORMATION (CONT'D)

DRUG INTERACTIONS

Use with Anticholinergics: Galantamine has the potential to interfere with the activity of anticholinergic medications.

ZUNVEYL (benzgalantamine) DELAYED RELEASE TABLETS 5 mg | 10 mg | 15 mg

Established Safety Profile

The safety profile of galantamine (the active ingredient of ZUNVEYL) has been established in 8 clinical trials[11]

Adverse Reactions Reported by ≥1% of Galantamine-Treated Patients in 8 Placebo-Controlled, Double-Blind Clinical Trials[11]

Adverse Reaction	Galantamine (n=3956) %	Placebo (n=2546) %
Metabolism and Nutrition Disorders		
Decreased appetite	7.4	2.1
Psychiatric Disorders		
Depression	3.6	2.3
Nervous System Disorders		
Dizziness	7.5	3.4
Headache	7.1	5.5
Tremor	1.6	0.7
Somnolence	1.5	0.8
Syncope	1.4	0.6
Lethargy	1.3	0.4
Cardiac Disorders		
Bradycardia	1.0	0.3
Gastrointestinal Disorders		
Nausea	20.7	5.5
Vomiting	10.5	2.3
Diarrhea	7.4	4.9
Abdominal pain	3.8	2.0
Abdominal discomfort	2.1	0.7
Dyspepsia	1.5	1.0
Musculoskeletal and Connective Tissue Disorders		
Muscle spasms	1.2	0.5
General Disorders and Administration Site Conditions		
Fatigue	3.5	1.8
Asthenia	2.0	1.5
Malaise	1.1	0.5
Investigations		
Decreased weight	4.7	1.5
Injury, Poisoning, and Procedural Complications		
Fall	3.9	3.0
Laceration	1.1	0.5

IMPORTANT SAFETY INFORMATION (CONT'D)

DRUG INTERACTIONS (CONT'D)

Use with Cholinomimetics and Other Cholinesterase Inhibitors: A synergistic effect is expected when cholinesterase inhibitors are given concurrently with succinylcholine, other cholinesterase inhibitors, similar neuromuscular blocking agents or cholinergic agonists such as bethanechol.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.

ZUNVEYL (benzgalantamine)
DELAYED RELEASE TABLETS
5 mg | 10 mg | 15 mg

No Significant Impact on Sleep

There was no significant difference between patients treated with galantamine (active ingredient of ZUNVEYL) and placebo across a broad range of sleep-related outcomes.

Post-Hoc Analysis of Sleep Outcomes from a Clinical Trial[23]

Pittsburgh Sleep Quality Index (PSQI) Subscales

Galantamine vs Placebo
Change from Baseline After 3 Months of Treatment

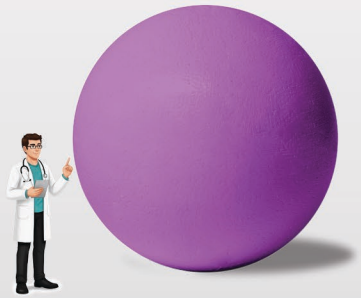
- ✓ Sleep disturbances
- ✓ Use of sleep medication
- ✓ Sleep duration
- ✓ Sleep latency
- ✓ Subjective sleep quality
- ✓ Habitual sleep deficiency
- ✓ Daytime dysfunction

No significant difference between patients treated with galantamine and placebo across a broad range of sleep-related outcomes.[23]

Results from post hoc analysis of a 3-month, multicenter, randomized, double-blind, placebo-controlled, flexible-dose trial of 261 patients with mild to moderate AD receiving 24 mg/day galantamine.

- The apparent neutral effect of galantamine on sleep is a positive consideration on treatment given the predisposition to sleep problems among individuals with AD.[23]
- Results support the absence of sleep problems with galantamine during pivotal clinical trials based on adverse event reporting.[23]
- Galantamine's short half-life, dual mechanism of action, and mode of binding to acetylcholinesterase may be the reasons for its minimal impact on sleep.[24,25]

The findings presented in this study are based on post-hoc analyses, which were not part of the original study design. As such, these results should be interpreted with caution.



IMPORTANT SAFETY INFORMATION (CONT'D)

USE IN SPECIFIC POPULATIONS

Pregnancy: Based on animal data may cause fetal harm.

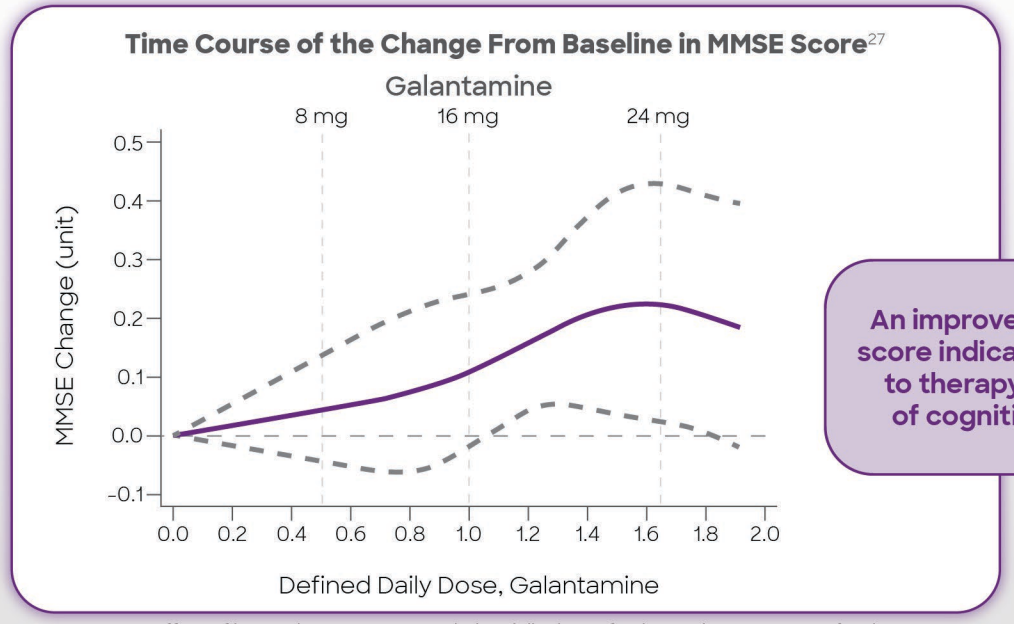
Hepatic Impairment: In patients with moderate hepatic impairment, a decrease in clearance of galantamine was observed; therefore, a dosage adjustment is recommended. Use of ZUNVEYL in patients with severe hepatic impairment is not recommended.

ZUNVEYL
(benzgalantamine)
DELAYED RELEASE TABLETS
5 mg | 10 mg | 15 mg

Reduction in Risk of Disease Progression

- In a 10-year, real-world, observational study, 39,196 patients with a diagnosis of Alzheimer's disease (AD) from the Swedish Dementia Registry were observed between 2007 and 2017.[26]
- Patients with AD starting on acetylcholinesterase inhibitors (AChEIs) within 3 months of the dementia diagnosis were compared with non-treated patients with AD over a 5-year average follow-up period. The association between AChEI use and cognitive change assessed by Mini-Mental State Examination (MMSE) scores was examined.[26]

Real-World, Observational Study



An improvement in MMSE score indicated a response to therapy or a slowing of cognitive decline*[26]

Dose-response effect of increasing average cumulative daily dose of galantamine to nonuse of AChEI: average (solid) and 95% confidence interval (dash-grey lines).[27]

* MMSE assesses orientation, language, attention and calculation, registration, and delayed recall of information.

Galantamine demonstrated a reduction in the risk of developing severe dementia (MMSE score <10; *P*=0.05)[26]

The findings presented in this study are based on longitudinal observational data. As such, these results should be interpreted with caution.

IMPORTANT SAFETY INFORMATION (CONT'D)

USE IN SPECIFIC POPULATIONS (CONT'D)

Renal Impairment: In patients with a creatinine clearance of 9 to 59 mL/min, an increase in exposure of galantamine was observed; therefore, a dosage adjustment is recommended. Use of ZUNVEYL in patients with creatinine clearance less than 9 mL/min is not recommended.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.

ZUNVEYL (benzgalantamine) DELAYED RELEASE TABLETS 5 mg | 10 mg | 15 mg

ZUNVEYL Dosing and Titration

Start at 5 mg, Increase to 10 mg

- The recommended starting dosage is 5 mg twice a day (10 mg/day) by mouth. Increase to initial maintenance dosage of 10 mg twice daily (20 mg/day) after a minimum of 4 weeks, based on clinical response and tolerability.[11]
  - Dosage may be increased to the maximum recommended dosage of 15 mg twice a day (30 mg/day) after a minimum of 4 weeks at 10 mg twice daily
- ZUNVEYL can be taken with or without food and should not be taken with alcohol.[11]
- Ensure adequate fluid intake during treatment.[11]
- **Tablets should be swallowed whole; do not split, crush or chew.**[11]

Swallow whole; do not split, crush or chew

Not actual size.

ZUNVEYL Recommended Dosing Schedule

Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9
5 mg BID	5 mg BID	5 mg BID	5 mg BID	10 mg BID	10 mg BID	10 mg BID	10 mg BID	15 mg BID

STARTING | MAINTENANCE | MAXIMUM IF NEEDED

- Galantamine (the active ingredient of ZUNVEYL) has a half-life of ~7 hours.[11]

Please see Dosage and Administration section of the full Prescribing Information for complete information on dosing.

ZUNVEYL can be ordered using facility prescription forms or EHR

- To order ZUNVEYL with titration, add specific instructions such as ***ZUNVEYL 5 mg/tablet BID x 28 days, then increase to 10 mg/tablet BID.***
- Including **"DAW," "Dispense as Written,"** or **"Medically Necessary"** helps ensure that residents get the medication that was prescribed.
- To add titration schedule to a ZUNVEYL order in an EHR system, **select ZUNVEYL Oral Tablet Delayed-Release option (no specific strength),** so both the starting and maintenance doses can be added at the same time.

EHR=electronic health record; BID=twice daily.

SELECT SAFETY INFORMATION

USE IN SPECIFIC POPULATIONS

Hepatic Impairment: In patients with moderate hepatic impairment, a decrease in clearance of galantamine was observed; therefore, a dosage adjustment is recommended. Use of ZUNVEYL in patients with severe hepatic impairment is not recommended.

ZUNVEYL (benzgalantamine) DELAYED RELEASE TABLETS 5 mg | 10 mg | 15 mg

ZUNVEYL Access Support for Residents and Providers

ZUNVEYL Prior Authorizations (PAs) Require Basic Criteria and Most Residents will have $0 Copay

ZUNVEYL Prior Authorization (PA) Key Criteria

- ✓ **Diagnosis specificity (ICD-10-CM alignment)**
  - Primary G-codes and/or supporting appropriate F-codes
- ✓ **Prior therapy history (if required by plan)**
  - Failure of previous medication (e.g., donepezil) due to intolerable adverse effects and/or lack of clinical benefit
- ✓ **Clinical rationale when step therapy may not be appropriate**
  - Pre-existing issues such as gastrointestinal conditions, sleep disturbances, and/or behavioral issues

ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification.

Note: Information is provided as courtesy only and is not comprehensive or instructive. Coverage and reimbursement depend on an individual resident's insurance plan.

Need Assistance with ZUNVEYL Prior Authorizations?

- Alpha Cognition is committed to supporting your residents. For assistance and/or additional resources, please contact your Access and Reimbursement Specialist at access@alphacognition.com.
- CoverMyMeds® is an online tool that lets prescribers send and track prior authorizations with insurance plans.Visit CoverMyMeds.health or call 1-866-452-5017.

Most residents in long-term nursing care will have

$0 copay*

*For Patients with Full-Benefit Dual Eligible Beneficiaries Institutionalized or Receiving Home and Community-Based Services

SELECT SAFETY INFORMATION

USE IN SPECIFIC POPULATIONS

Renal Impairment: In patients with a creatinine clearance of 9 to 59 mL/min, an increase in exposure of galantamine was observed; therefore, a dosage adjustment is recommended. Use of ZUNVEYL in patients with creatinine clearance less than 9 mL/min is not recommended.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.

ZUNVEYL (benzgalantamine)
DELAYED RELEASE TABLETS
5 mg | 10 mg | 15 mg

ZUNVEYL: A Clear Choice for Your Residents with AD

Purposefully Designed Delivery

- Enteric-coated, delayed-release prodrug technology designed to minimize absorption in the stomach and avoid overstimulation of the gastrointestinal nervous system.[11,12]
- Provides dual protection from peripheral and central cholinergic side effects.[12]

Dual Acting Mechanism of Action†

- Inhibits acetylcholinesterase, preventing the breakdown of acetylcholine and increasing its availability.[11]
- Modulates nicotinic acetylcholine receptors, making acetylcholine pathways more responsive.[14,15]

†The mechanism of action of ZUNVEYL is not fully understood.

Proven Medication for Cognition, Behaviors and Daily Function

- Galantamine (the active ingredient of ZUNVEYL) showed significant and sustained improvement in cognition, behaviors, and functional performance.[11,21]
- Patients treated with galantamine demonstrated statistically significant reductions in the risk of severe dementia.[26]

No Significant Impact on Sleep

- No significant difference between patients treated with galantamine and placebo across a broad range of sleep-related outcomes.[23]
- No incidence of insomnia in the ZUNVEYL label.[11]

Scan the QR code to visit Zunveyl.com for access support and additional resources

INDICATION AND USAGE

ZUNVEYL is a cholinesterase inhibitor indicated for the treatment of mild to moderate dementia of the Alzheimer's type in adults.

SELECT SAFETY INFORMATION

ADVERSE REACTIONS

The most common adverse reactions with galantamine tablets (≥5%) were nausea, vomiting, diarrhea, dizziness, headache, and decreased appetite.

ZUNVEYL
(benzgalantamine)
DELAYED RELEASE TABLETS
5 mg | 10 mg | 15 mg

REFERENCES: **1.** Jost BC, Grossberg GT. *J Am Geriatr Soc*. 1996;44(9):1078-81. **2.** Cummings JL, Back C. *Am J Geriatr Psychiatry*. 1998;6(2 Suppl 1):S64-78. **3.** Naharci MI, et al. *Acta Neurol Belg*. 2015;115(4):563-568. **4.** Bombois S, et al. *J Nutr Health Aging*. 2010;14(3):212-217. **5.** Dauvilliers Y. *Sleep Med*. 2007;8 Suppl 4:S27-S34. **6.** Gaugler JE, et al. *J Gerontol B Psychol Sci* Soc Sci. 2000;55(4):P247-P255. **7.** Ownby RL, et al. *Am J Geriatr Psychiatry*. 2014;22(2):148-156. **8.** Cummings JL. *Focus*. 2004;2(2):239-252. **9.** Campbell NL, et al. *J Am Geriatr Soc*. 2017;65(7):1497-1504. **10.** Data on File, Alpha Cognition; Grapevine, TX (LTC market research survey by 2 Infinity Group 2021). **11.** ZUNVEYL (benzgalantamine) delayed-release tablets [Prescribing Information]. Grapevine, TX. Alpha Cognition Inc. 2024. **12.** Data on File, Alpha Cognition; Grapevine, TX (ZUNVEYL IND Components of the Drug Product). **13.** Liederer BM, Borchardt RT. *J Pharm Sci*. 2006;95(6):1177-1195. **14.** Lilienfeld S. *CNS Drug Rev*. 2002;8(2):159-176. **15.** Ago Y, et al. *J Pharmacol Sci*. 2011;116(1):6-17. **16.** Data on File, Alpha Cognition; Grapevine, TX (ZUNVEYL Registration Trials Summary 2024). **17.** Data on File, Alpha Cognition; Grapevine, TX (ALPHA-1062-01 Fed). **18.** Data on File, Alpha Cognition; Grapevine, TX (ALPHA-1062-02 Fasted). **19.** Data on File, Alpha Cognition; Grapevine, TX (ALPHA-1062-03 Steady State). **20.** Data on File, Alpha Cognition; Grapevine, TX (ALPHA-1062-04 Dose Proportionality). **21.** Tariot PN, et al; Galantamine USA-10 Study Group. *Neurology*. 2000;54(12):2269-2276. **22.** Cummings JL. Neuropsychiatric Inventory (NPI): instructions for use and administration. Mary S. Easton Center for Alzheimer's Disease Research at UCLA; 2009. **23.** Markowitz JS, et al. *Sleep*. 2003;26(5):602-606. **24.** Stahl SM, et al. *Curr Med Res Opin*. 2004;20(4):517-524. **25.** Cummings JL. *Am J Psychiatry*. 2000;157(1):4-15. **26.** Xu H, et al. *Neurology*. 2021;96(17):e2220-e2230. **27.** Xu H, et al. *Neurology*. 2021;96(17):e2220-e2230; supplementary tables/figures.

ZUNVEYL
(benzgalantamine)
DELAYED RELEASE TABLETS
5 mg | 10 mg | 15 mg