GE HealthCare

VIZAMYL™
Flutemetamol F18
Injection

We are dedicated to providing comprehensive coverage and access support for your patient.

1

Support starts with the Vizamyl Patient Referral Form. Available from:

- Your Account Manager
- Via the Vizamyl website at **gehealthcare.com/vizamyl**
- Call the Vizamyl Support Center at **844 225 1595**
- Email the Vizamyl Support Center at **gehealthcare@pharmacord.com**

2

The Vizamyl Support Center supports the entire reimbursement journey
Live support: 844 225 1595 (Mon-Fri, 8AM to 6PM ET)

Benefit Investigations
- Verifying a patient's in-network health insurance coverage

Billing and Coding Assistance
- Guidance for billing and coding requirements

Claims Assistance
- Help in navigating through the claims process

Pre-Service and Post-Service Appeals
- Assistance with expediting these appeals

Prior Authorizations Support and Status Monitoring
- Help with initiating and monitoring prior authorization requests from insurance companies (prefilled patient and physician demographics)

Medical Necessity Assistance
- Guidance on how to navigate the medical necessity requirements for the Payor

Peer-to-Peer Preparation
- Provide training for HCP engagement for upcoming Payer Peer-to-Peer discussions

Vizamyl Imaging Center Locator
- Support in finding in-network imaging center(s)

3

A dedicated Field Reimbursement Manager (FRM) is available to your office:

- Can provide onboarding when preparing your office to prescribe Vizamyl
- Can provide your billing staff with inservice reimbursement training
- Can provide payor-specific answers on Vizamyl coding and billing questions
- Can engage the GE HealthCare Managed Market Payor Executives for payor-specific challenges

Please see Important Safety Information About Vizamyl on reverse and enclosed full Prescribing Information.

GE HealthCare

PRODUCT INDICATION AND USE

Vizamyl is a radioactive diagnostic agent indicated for Positron Emission Tomography (PET) imaging of the brain to estimate β-amyloid neuritic plaque density in adult patients with cognitive impairment who are being evaluated for Alzheimer's disease (AD) or other causes of cognitive decline. A negative Vizamyl scan indicates sparse to no neuritic plaques, and is inconsistent with a neuropathological diagnosis of AD at the time of image acquisition; a negative scan result reduces the likelihood that a patient's cognitive impairment is due to AD. A positive Vizamyl scan indicates moderate to frequent amyloid neuritic plaques; neuropathological examination has shown this amount of neuritic plaque is present in patients with AD, but may also be present in patients with other types of neurologic conditions, as well as older people with normal cognition. Vizamyl is an adjunct to other diagnostic evaluations

Limitations: A positive scan does not establish a diagnosis of AD or other cognitive disorder. The safety and effectiveness of Vizamyl have not been established for predicting the development of dementia or other neurologic conditions or for monitoring responses to therapies.

IMPORTANT SAFETY INFORMATION ABOUT VIZAMYL™

CONTRAINDICATIONS

- Known hypersensitivity to Vizamyl or any excipient, including polysorbate 80.

WARNINGS AND PRECAUTIONS

- **Hypersensitivity Reactions:** Reactions such as flushing and dyspnea have been observed within minutes following administration and may occur in patients with no history of exposure to Vizamyl. Before administering Vizamyl, ask patients about prior reactions to drugs, especially those containing polysorbate 80. Have resuscitation equipment and trained personnel available.
- **Risk for Image Misinterpretation and Other Errors:** Errors may occur while interpreting Vizamyl positron-emission tomography (PET) images. Image interpretation is performed independently of the patient's clinical information. The use of clinical information in the interpretation of Vizamyl images has not been evaluated and may lead to errors. Extensive brain atrophy may limit the ability to distinguish grey and white matter on a Vizamyl scan. Motion artifacts may distort the image. Images should be interpreted only by readers who have completed a reader training program available from GE Healthcare
- **Radiation Risk:** Like all radiopharmaceuticals, Vizamyl contributes to a patient's long-term, cumulative radiation exposure and cancer risk. Ensure safe handling to protect patients and healthcare workers from unintentional radiation exposure.

ADVERSE REACTIONS

- The most commonly reported adverse reactions in clinical trials were flushing (2%), increased blood pressure (2%), headache (1%), nausea and dizziness (1%)

DRUG INTERACTIONS

- Drug-drug interaction studies have not been performed in patients to establish the extent, if any, to which concomitant medications may alter Vizamyl image results.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** All radiopharmaceuticals, including Vizamyl, have potential to cause fetal harm. There are no available data on Vizamyl in pregnant woman to evaluate drug associated risk of major birth defects, miscarriage or adverse maternal or fetal outcome Advise women about the potential for adverse pregnancy outcomes based on the radiation dose and gestational timing of exposure
- **Lactation:** There are no data on presence of flutemetamol or its metabolites in human milk. The benefits of breastfeeding should be considered along with the mother's clinical need for Vizamyl and any potential adverse effects on the breastfed child. Because many drugs are excreted in human milk and there is a potential for radiation exposure to nursing infants, advise a lactating woman to interrupt breastfeeding and pump and discard breast milk for 24 hours after administration to minimize radiation exposure to a breastfeeding infant
- **Pediatric Use:** Vizamyl is not indicated for use in pediatric patients
- **Geriatric Use:** No overall differences in safety were observed between older and younger subjects

OVERDOSAGE

- The clinical consequence of overdosing with Vizamyl has not been reported. It is unknown whether or not flutemetamol is dialyzable. The major risks of overdosage relate to increased radiation exposure and long-term risk for neoplasia. In case of overdose of radioactivity, hydration and frequent urination should be encouraged.

Prior to Vizamyl administration, please read the enclosed full Prescribing Information, for additional Important Safety Information.

To report SUSPECTED ADVERSE REACTIONS, contact GE HealthCare at 800 654 0118 (option 2, then option 1) or the FDA at 800 FDA 1088 or www.fda.gov/medwatch.

RESOURCES

Customer Service: 800 292 8514

Vizamyl Support Center: 844 225 1595

Medical Affairs for Clinical and Scientific Support:
800 654 0118. (option 2, then option 3) or
medical.affairs@ge.com

gehealthcare.com

VIZAMYL™
Flutemetamol F18
Injection

September 2023 JB09025US Printed in USA