

## Product Indications and Important Safety Information – Vizamyl

### PRODUCT INDICATIONS AND USE

VIZAMYL™ (Flutemetamol F 18 Injection) is indicated for positron-emission tomography (PET) imaging of the brain to estimate  $\beta$ -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 scan indicates sparse to no neuritic plaques, inconsistent with a 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 scan indicates moderate to frequent amyloid neuritic plaques. This amount of amyloid neuritic plaque has been shown to be present in patients with AD but may also be present in patients with other neurologic conditions as well as in 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™ (Flutemetamol F 18 Injection)

#### 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 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](http://www.fda.gov/medwatch).**