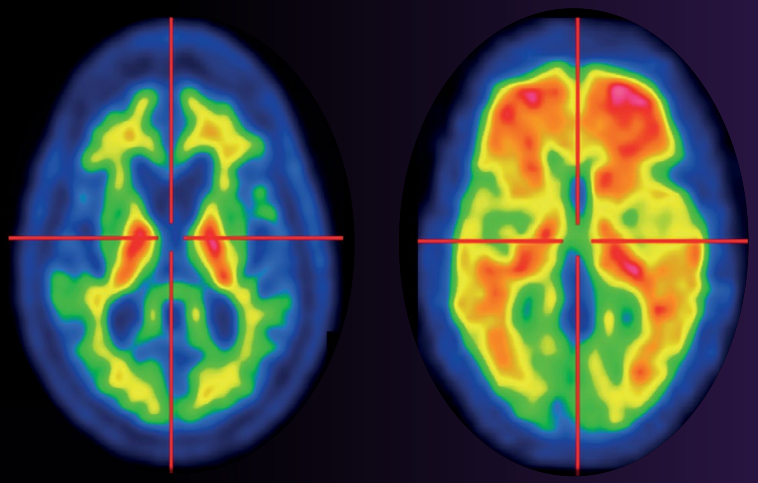
GE HealthCare



Insight-Driven Imaging. Delivered in full color.

Putting the potential of amyloid imaging into practice

PRODUCT INDICATIONS AND USE

VIZAMYL™ (Flutemetamol F 18 Injection) is 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 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.

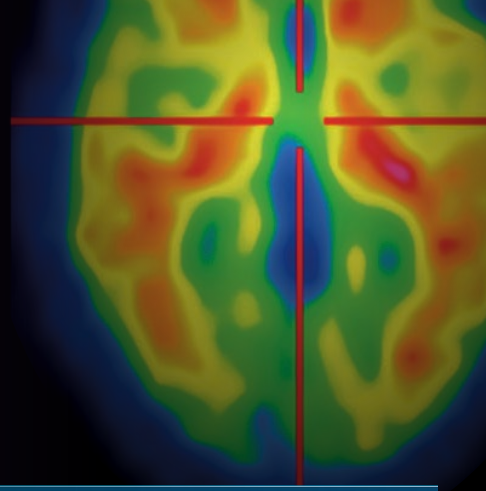
IMPORTANT SAFETY INFORMATION ABOUT VIZAMYL™ (FLUTEMETAMOL F 18 INJECTION)
CONTRAINDICATIONS

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

Please see Important Safety Information on page 15 and enclosed Full Prescribing Information.

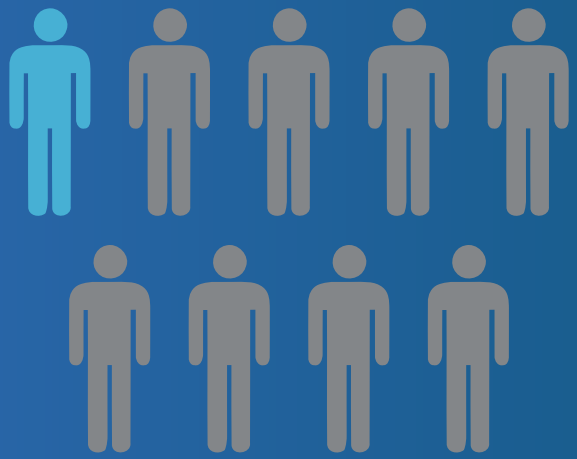
An unmet clinical challenge

Alzheimer's disease (AD) is the most common cause of dementia, accounting for 60% to 80% of cases[1]



One in nine people (11%)

65 years of age or older currently has AD[1]



In 2022, an estimated

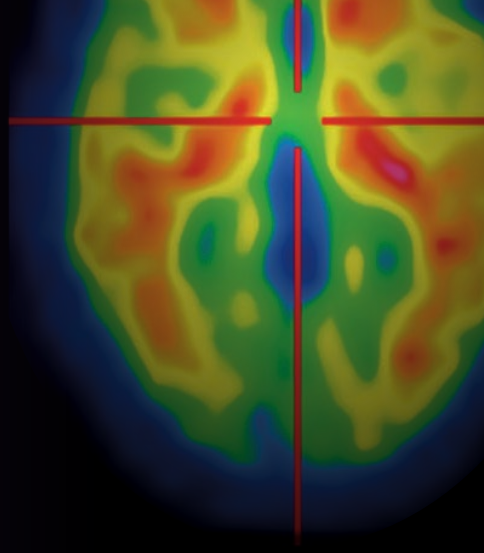
6.5 million

Americans age 65 and older are living with AD[1]

AD is the **5th leading cause of death** in Americans 65 or older[1]

VIZAMYL™
Flutemetamol F18 Injection

The only amyloid imaging agent with FDA approval for color image interpretation as an adjunct to other evaluations



Vizamyl™ (Flutemetamol F-18 Injection) is an adjunct to other diagnostic evaluations, and is indicated for PET imaging of the brain to estimate β-amyloid neuritic plaque density in adult patients with cognitive impairment who are being evaluated for AD and other causes of cognitive decline.[2]

A NEGATIVE VIZAMYL SCAN indicates sparse to no neuritic plaques and is inconsistent with a neuropathological diagnosis of AD at the point of image acquisition

A negative scan 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 that this amount of amyloid neuritic plaque is present in patients with AD; however, it may also be present in patients with other types of neurologic conditions as well as in older people with normal cognition

Limitations of use

- A positive Vizamyl scan does not establish a diagnosis of AD or other cognitive disorders
- Safety and effectiveness of Vizamyl have not been established for:
  - Predicting development of dementia or other neurological conditions
  - Monitoring responses to therapies

AD, Alzheimer's disease; **PET,** positron-emission tomography.

PRODUCT INDICATIONS AND USE

VIZAMYL™ (Flutemetamol F 18 Injection) is 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 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.

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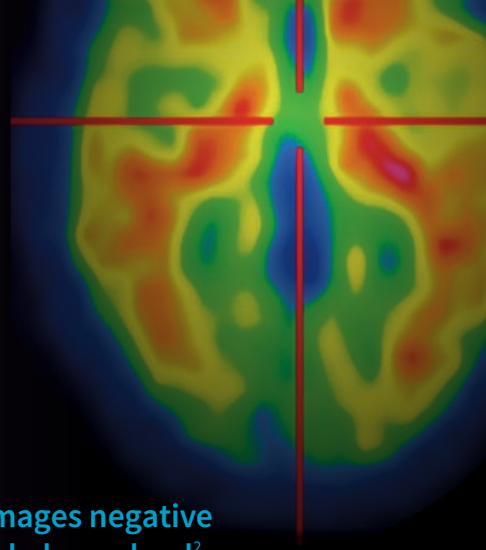
VIZAMYL™ Flutemetamol F18 Injection

The clinical value of amyloid imaging with precise color scaling

Vizamyl may help to support clinical assessment[2]

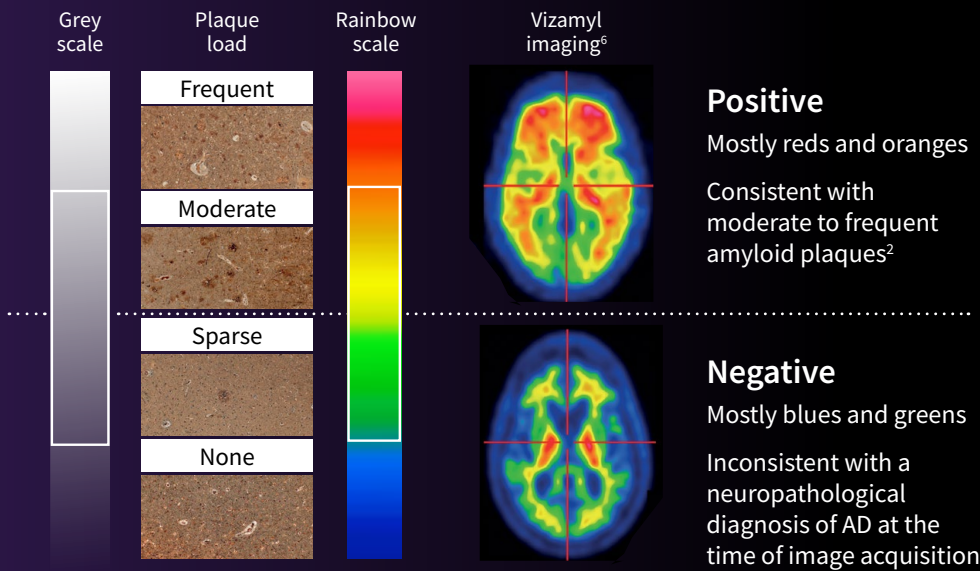


Median Sensitivity: 88%

Median Specificity: 88%

n=68
Scan results after in person reader training among patient with autopsy

Vizamyl color imaging assists in differentiation of images negative for amyloid plaque from images positive for amyloid plaque load[2]



Positive

Mostly reds and oranges

Consistent with moderate to frequent amyloid plaques[2]

Negative

Mostly blues and greens

Inconsistent with a neuropathological diagnosis of AD at the time of image acquisition[2]

AD, Alzheimer's disease.

IMPORTANT SAFETY INFORMATION ABOUT VIZAMYL

CONTRAINDICATIONS

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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

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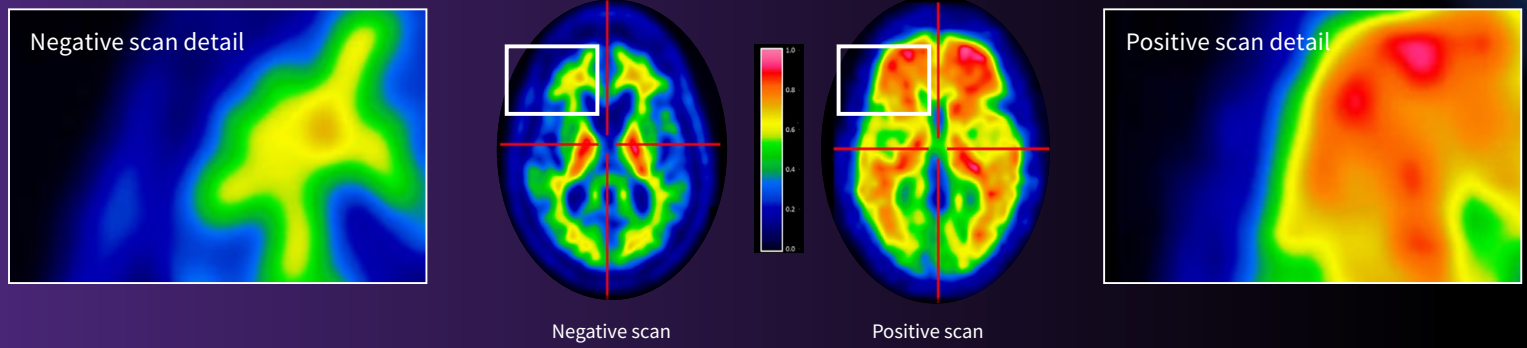
VIZAMYL™ Flutemetamol F18 Injection

Cortical uptake is associated with a shift from blues and greens to oranges and reds



Mostly blues and greens

- Little to no amyloid plaque density[2]
- Tracer uptake consistent with white matter pattern
- Gradual change in color gradient toward the edge of the brain tissue

Mostly oranges and reds

- Moderate to high amyloid plaque density in the grey matter[2]
- Tracer uptake in amyloid plaques located within the grey matter
- Abrupt change in color gradient at the edge of the brain

Images on file; GE HealthCare.

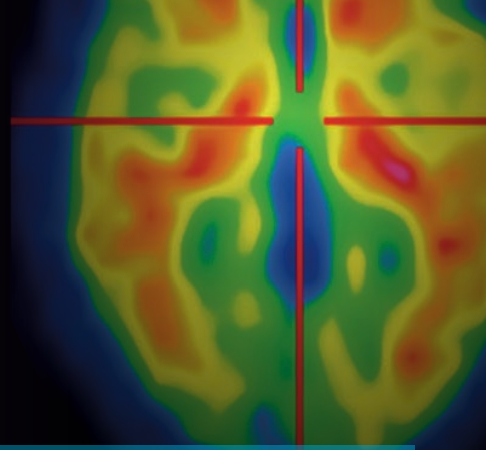
IMPORTANT SAFETY INFORMATION ABOUT VIZAMYL
WARNINGS AND PRECAUTIONS

- **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

Please see Important Safety Information on page 15 and enclosed Full Prescribing Information.

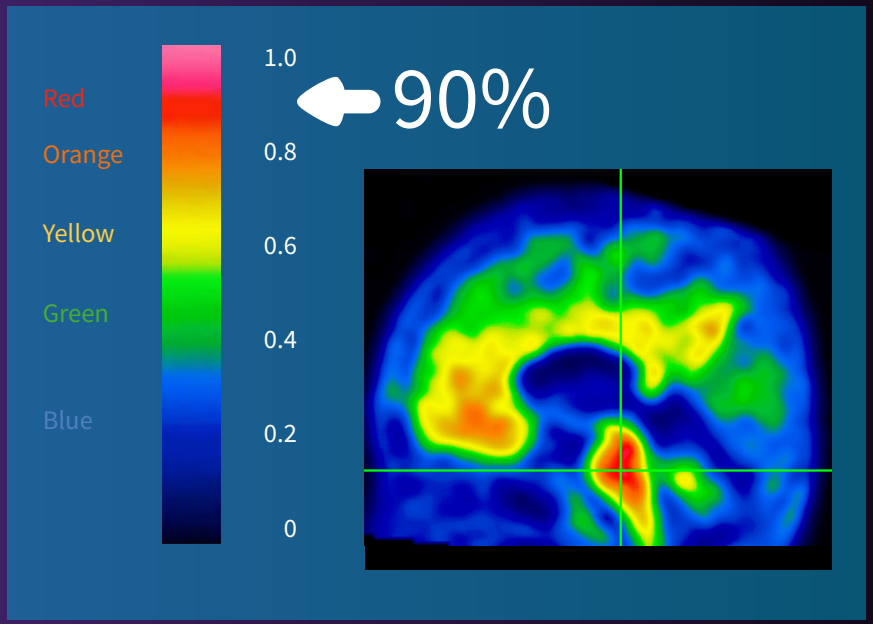
VIZAMYL™ Flutemetamol F18 Injection

Enabling consistency and clinical diagnostic certainty in interpretation of scans



Set pons to 90% (red in this color scale) to establish an anchor point for scaling in all images

- *Pons set to red (90%)*
- *Reference intensity for the rest of the brain*
- *Helps consistency in interpretation of scans*



Regional review methodology may help improve diagnostic certainty

- A scan is deemed positive if any one or more of the 5 review regions is positive:
  - Frontal, Lateral Temporal, Posterior Cingulate/ Precuneus, Inferolateral Parietal and Striatum.

- Pons uptake of flutemetamol (F18) in negative and positive cases is comparable
- When all images are scaled to pons at 90% of maximum image intensity, it enables interpretation of white and grey matter uptake within and between cases

Images on file; GE HealthCare.

IMPORTANT SAFETY INFORMATION ABOUT VIZAMYL
WARNINGS AND PRECAUTIONS

- **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

Please see Important Safety Information on page 15 and enclosed Full Prescribing Information.

VIZAMYL™ Flutemetamol F18 Injection

As an adjunct to clinical workup, imaging with Vizamyl can assist in ruling out AD, helping to more quickly determine the appropriate clinical path for your patient

Visualize β-amyloid buildup in color

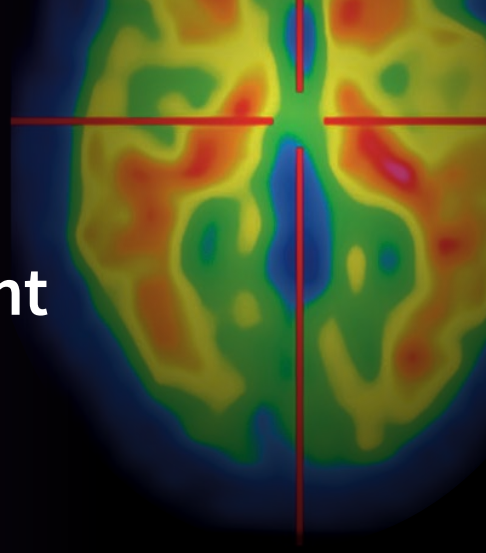
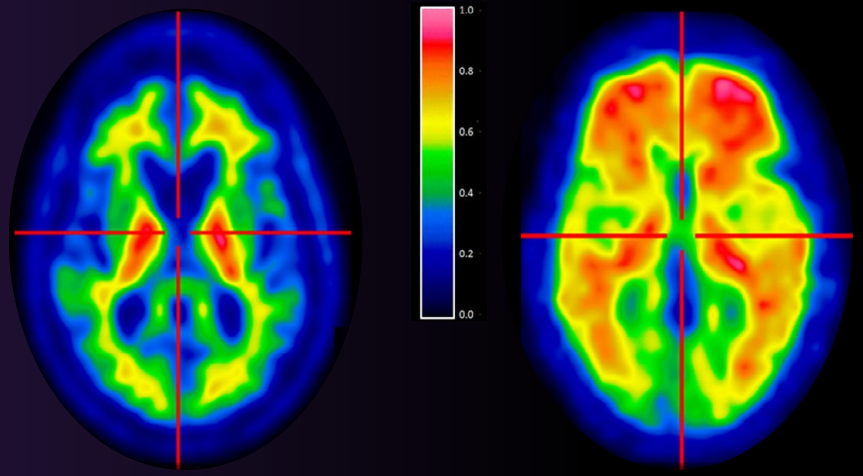


Image interpretation is performed by visually comparing activity in cortical grey matter with activity in adjacent white matter[2]

- Color images provide a visualization of flutemetamol uptake that can be shared with referring physicians, patients, and caregivers to help enhance communication



Negative Scan

Positive Scan

Images on file; GE HealthCare.

AD, Alzheimer's disease.

IMPORTANT SAFETY INFORMATION ABOUT VIZAMYL
WARNINGS AND PRECAUTIONS

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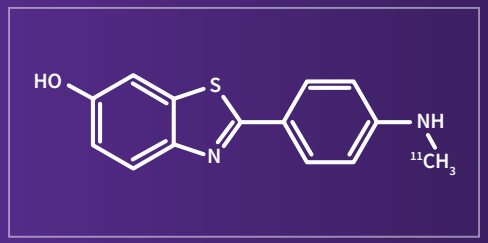
VIZAMYL™ Flutemetamol F18 Injection

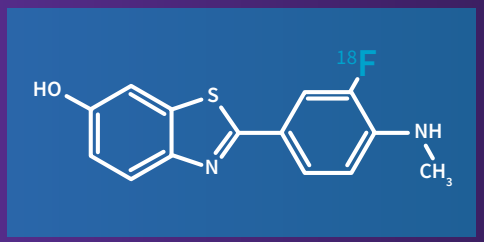
Building on PiB heritage –

The amyloid PET tracer that has been studied in AD since 2002[3]

Vizamyl has demonstrated equivalent cortical uptake to PiB[4-(pg7)]

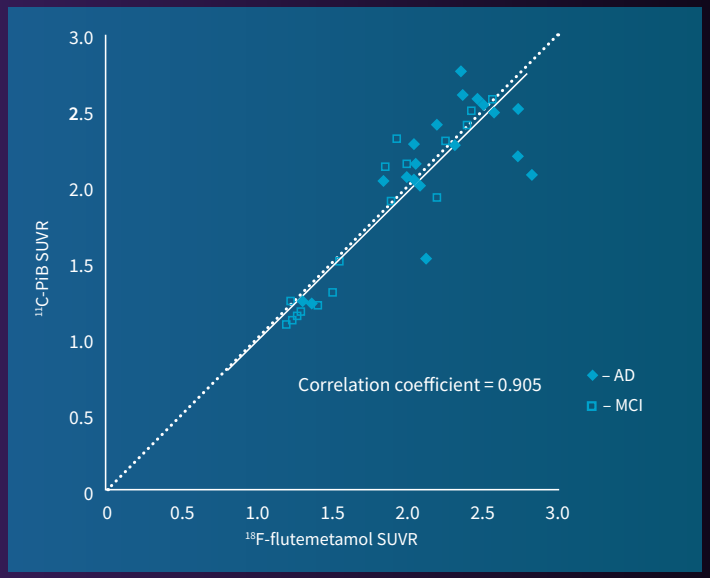


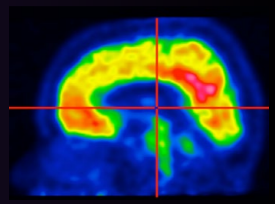
PiB



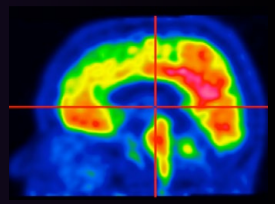
Vizamyl

Correlation between PiB and Vizamyl SUVR from 20 AD and 20 MCI subjects, composite cortical region[4]





PiB imaging



Vizamyl imaging

Reprinted from *Annals of Neurology*. 2010; 68(3): 319-29. Vandenberghe R et al. 18F-flutemetamol amyloid imaging in Alzheimer disease and mild cognitive impairment: A phase 2 trial. © 2010 John Wiley and Sons. Images on file; GE HealthCare.[4-(pg7)]

AD, Alzheimer's disease; **PET,** positron-emission tomography; **MCI,** mild cognitive impairment; **PiB,** Pittsburgh compound B; **SUVR,** standardized uptake value.

IMPORTANT SAFETY INFORMATION ABOUT VIZAMYL
WARNINGS AND PRECAUTIONS

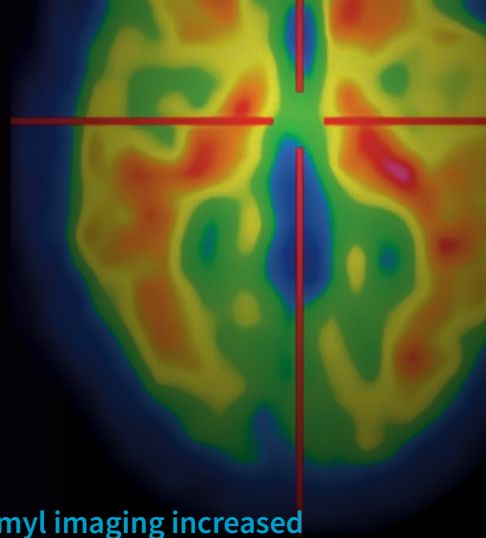
- **Radiation Risk**: Like all radiopharmaceuticals, Vizamyl contributes to a patient's long-term, cumulative radiation exposure and cancer risk. Ensure safe handling to protect patients and healthcare workers from unintentional radiation exposure

Please see Important Safety Information on page 15 and enclosed Full Prescribing Information.

VIZAMYL™ Flutemetamol F18 Injection

The real-world impact of Vizamyl

In order to investigate the role of Vizamyl and the difference it may make in terms of diagnostic confidence and patient management, a prospective study was performed[2,5]



Patients with suspected dementia were diagnosed clinically, then received Vizamyl imaging[5]

Patients had:	*Clinical diagnosis*	
• Early onset dementia • Mild dementia • Uncertain diagnosis	AD n=144	Non-AD n=67

Vizamyl imaging led to changes in diagnosis and patient management plan in a substantial proportion of patients[5]

Change in diagnosis 19% n=41

No change in diagnosis 81% n=170

Change of management plan 37% n=79

No change in management plan 63% n=132

Results from Vizamyl imaging increased physician confidence in their diagnosis from 69% to 88% in 87% of patients[5]

These results support the recommendations of the appropriate use criteria:

Amyloid pet is appropriate in the diagnosis of early-onset dementia or patients with unexplained MCI or who satisfy core clinical criteria for possible AD with an atypical presentation[5]

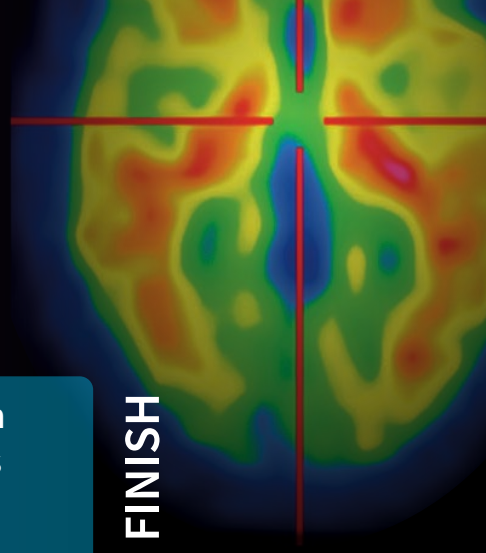
AD, Alzheimer's disease.

Please see Important Safety Information on page 15 and enclosed Full Prescribing Information.

VIZAMYL™ Flutemetamol F18 Injection

Increase imaging flexibility

Summary of the imaging process with Vizamyl



IV PLACEMENT

START

Wait
60 – 120 minutes

PET Acquisition
10 – 20 minutes

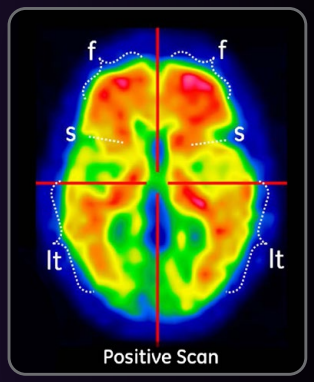
FINISH

Injection
≤10 mL dose per patient at an activity of 5 ± 10% mCi

- Administer as a slow single IV bolus within 40 seconds
- Follow with an IV flush of 5 mL to 15 mL of 0.9% sterile sodium chloride injection

Patients are not restricted to the imaging center during this time.

- Option for patient to return to family or caregivers, have lunch, run errands, restroom break, and other similar activities



f, frontal; **s,** striatal; **lt,** lateral temporal.
Representative positive scan; scans will vary.
Images displayed using the rainbow color scale.

CT, computed tomography; **IV,** intravenous; **PET,** positron-emission tomography.

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.

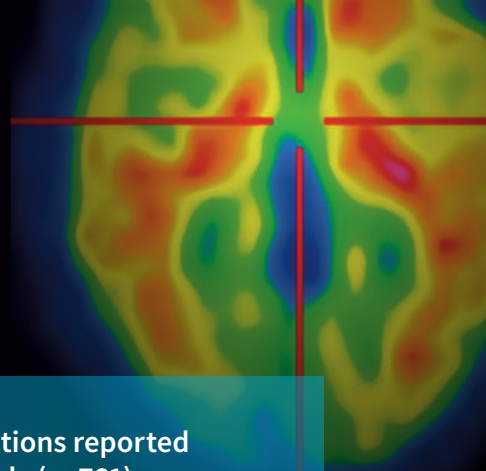
IMPORTANT SAFETY INFORMATION ABOUT VIZAMYL
WARNINGS AND PRECAUTIONS

- **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

Please see Important Safety Information on page 15 and enclosed Full Prescribing Information.

VIZAMYL™
Flutemetamol F18
Injection

Safety of Vizamyl demonstrated in clinical trials



In clinical trials of 761 patients dosed, one subject experienced a serious hypersensitivity reaction[2]

- This reaction was accompanied by flushing, dyspnea, and chest pressure
- The reaction occurred within minutes of Vizamyl administration, and the patient symptoms resolved after administration of epinephrine. The patient then completed the imaging exam

Radiation safety

- The recommended dose is 185 MBq (5 mCi) injected intravenously[2]
- The effective adult dose from the administration of 185 MBq (5 mCi) of Vizamyl is 5.92 mSv[2]
- Concomitant use of a CT scan will add radiation exposure (up to an average of 2.2 ± 1.3 mSv). Actual radiation dose is operator- and scanner-dependent

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 reported in clinical trials (n=761)

Adverse Reaction	n (%)
Flushing	16 (2%)
Increased blood pressure	13 (2%)
Headache	10 (1%)
Nausea	8 (1%)
Dizziness	8 (1%)

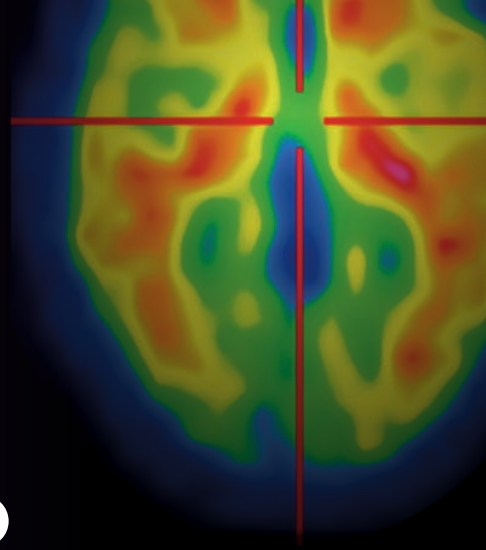
The most commonly reported adverse reactions occurred at a rate of ≤2% and were of mild to moderate intensity.[2]

CT, computed tomography.

Please see Important Safety Information on page 15 and enclosed Full Prescribing Information.

VIZAMYL™ Flutemetamol F18 Injection

Patients, caregivers, and healthcare providers may all benefit from a timely diagnosis of dementia syndromes



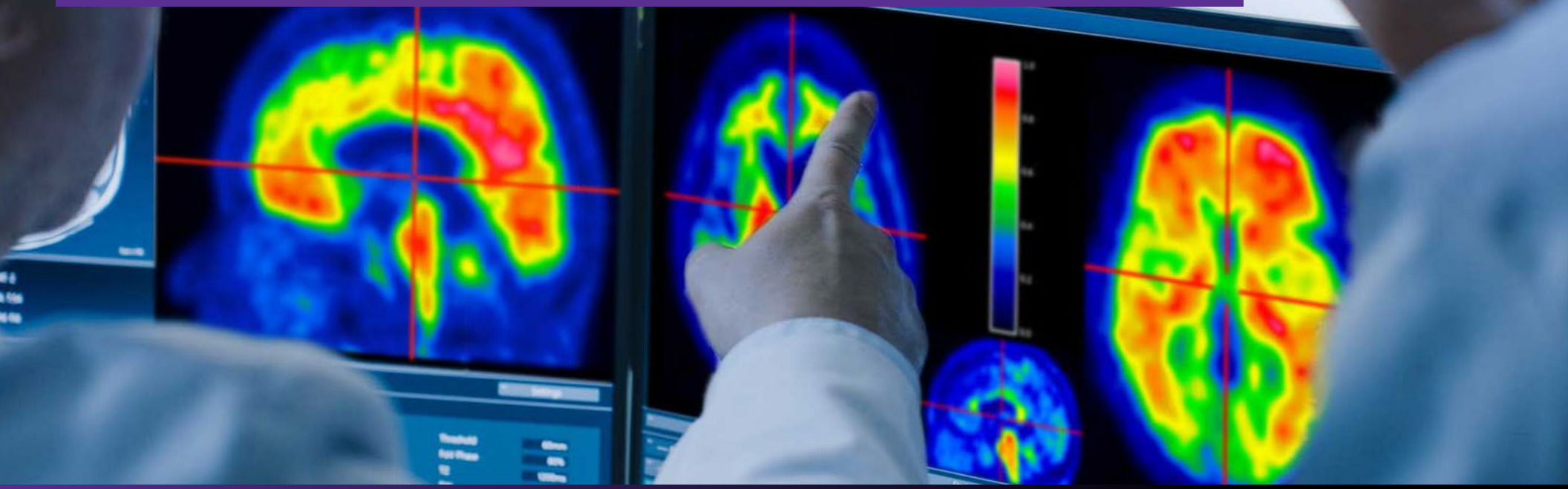
The *IDEAS Study,* which included 11,409 patients with MCI or dementia who underwent amyloid PET scans, highlights the importance of timely diagnoses. Following a PET scan:[7]

- There was **change in clinical management for ~60% of patients** (drug therapy or consulting for future planning) within 90 days
- **Diagnosis changed** from non-AD to AD in **1,201 patients**
- **Diagnosis changed** from AD to non-AD in **~25% of patients** (n=2860)

AD, Alzheimer's disease; **MCI,** mild cognitive impairment.

Vizamyl Electronic Reader Training Program

GE HealthCare offers a complimentary online reader training program to aid in the interpretation of Vizamyl positron-emission tomography (PET) images in color. Vizamyl images should be interpreted only by readers who successfully completed this program.

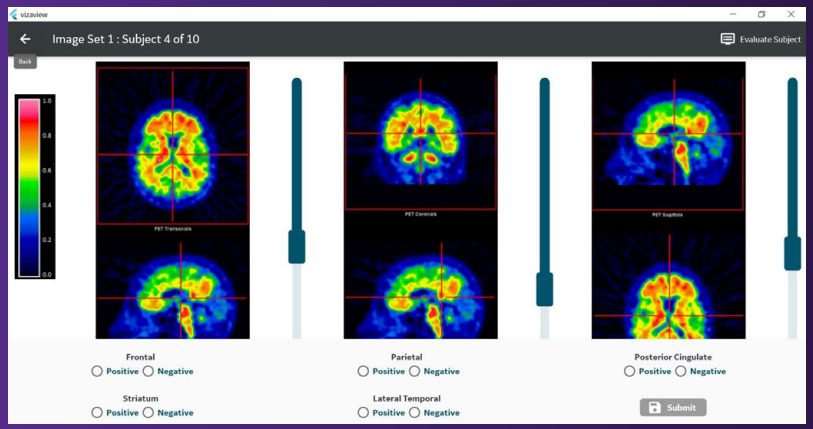


VIZAMYL™
Flutemetamol F18
Injection

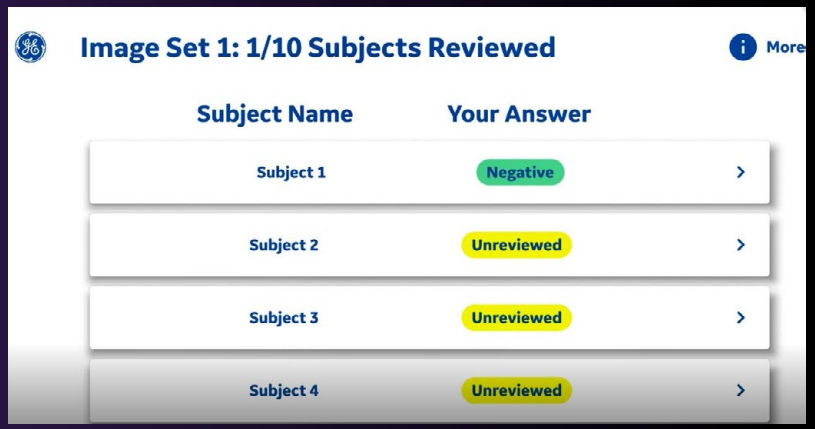
VizaView: A case-based review application

Now available for download in the App Store

VizaView is a case-based review application designed to enhance proficiency and improve confidence of trained readers in the interpretation of amyloid imaging cases using Vizamyl.



Enhance your proficiency by evaluating cases.



Review real-time results and receive detailed explanations of incorrect answers.

VIZAMYL™ Flutemetamol F18 Injection

PRODUCT INDICATIONS AND USE

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IMPORTANT SAFETY INFORMATION ABOUT VIZAMYL™ (FLUTEMETAMOL F 18 INJECTION)

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

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- **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.

VIZAMYL™
Flutemetamol F18
Injection

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Please see Important Safety Information on page 15 and enclosed Full Prescribing Information.

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