

Alzheimer's Care With Full-Color Diagnosis

Early and accurate detection is key in the fight against Alzheimer's disease.

By Dash Lunde

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This often causes delays in effective therapies because Alzheimer's patients may be engaged in treatment plans that target a different form of dementia. These challenges of diagnosis are a particular burden on patients and caregivers, who may struggle with anxiety over a potentially life-changing diagnosis.

One hallmark of Alzheimer's is clumps of amyloid plaque in the memory and decision-making areas of the brain. Medical professionals have made progress, using drugs that can bind with plaque buildups and can display them through medical positron-emission tomography (PET) scans.

"Up to one-third of patients who were enrolled in clinical trials have had negative amyloid scans," explains John C. Morgan, MD, PhD, of the Medical College of Georgia. Clinical trials are the key to new therapies, and researchers need to be sure that they're treating the right illness.

An improved methodology

A neuroimaging agent from GE Healthcare is now helping to ensure that the reading and communication of amyloid PET scans is no longer a gray area. This agent, known as VizamyTM (Flutemetamol F 18 Injection), easily passes into brain tissue and attaches to amyloid plaque. The resulting contrast between normal or diseased brain allows your physician to accurately identify the presence of brain amyloid.

Your doctor will use this information, along with other tests, to try to better understand your condition. A Vizamy test by itself cannot tell if you have or will get a condition like Alzheimer's, or tell how well any treatment you are on may be working.

Furthering the fight

With a special color scale, physicians and scientists are able to see the flutemetamol bound to the amyloid in the brain using the PET scan. This development marks the first neuroimaging agent approved by the U.S. Food & Drug Administration for color methodology. While predecessors were designed for black-and-white or grayscale reading, Vizamy is designed for color.

Color images can help educate patients and caregivers, thereby assisting physicians to formulate appropriate treatment plans. Vizamy, along with clinical evaluation, may allow researchers to more effectively recruit patients for enrollment in clinical trials that are right for them.

"I'm consistently surprised by how patients are able to relate to these images more," says Norman Foster, MD, Senior Investigator at the Brain Institute of The University of Utah. "This really helps facilitate our conversations — it's revolutionary."

Early detection may also offer hope in the prevention of disease. It's much easier to prevent a disease than to undo damage. So,

finding a way to intervene at the first sign of amyloid buildup can help us better fight the disease. ■

To learn more about Vizamy, please see Brief Summary on page 8 and visit www.gevizamy.com/us

Important Risk and Safety Information About Vizamy

What is Vizamy?

Vizamy is a radioactive drug that is injected into your bloodstream to help take an image of your brain. This image is taken using a special camera (called a PET camera). If you are an adult who has been having trouble remembering or thinking clearly, and you are being tested for conditions like Alzheimer's disease (AD), your doctor may decide to do an imaging test using Vizamy. This test can determine whether there is a protein called beta-amyloid in your brain. Your doctor will use this information, along with other tests, to try to better understand your condition. A Vizamy test by itself cannot tell if you have or will get a condition like AD, or tell how well any treatment you are on may be working.

You should not take Vizamy if:

- You are sensitive to polysorbate 80 or any other ingredients of Vizamy. Your doctor can help

you understand what these compounds are

What warnings should I know about Vizamy?

- Vizamy can cause reactions such as flushing or shortness of breath. Be sure to tell your doctor if you have had reactions to other drugs, especially any that contain polysorbate 80
- Like other radioactive drugs, Vizamy adds to your lifetime radiation exposure. Long-term radiation exposure is related to increased risk of cancer

What are the most common side effects of Vizamy?

- Flushing, increased blood pressure, headache, nausea, or dizziness has occurred in one out of every 50 patients

What should you know about taking Vizamy with other medications?

- Studies have not been conducted to show which, if any, drugs may interfere with the Vizamy test results. Be sure to tell your doctor what drugs you are taking so that he or she can decide whether you should stop any of them for a period of time before your Vizamy test

Always talk with your doctor if you have any questions about PET imaging or Vizamy.

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Would you rather see the world in color or in shades of gray? When it comes to an Alzheimer's diagnosis, for far too long it's been the latter. While grayscale only conveys the intensity of light, different colors represent physically distinct wavelengths. These colors can be instrumental in helping many patients who don't notice the effects of the disease — until after significant damage has already been done. The process of plaque buildup that causes the disease can be ongoing for anywhere from 10 to 20 years before symptoms begin to manifest.

Finding early indicators

Even when patients do suffer from noticeable memory loss, a diagnosis of Alzheimer's won't be immediate. Cognitive impairment may be due to metabolic and cardiovascular conditions as well as depression, and these causes need to be ruled out before a diagnosis of Alzheimer's disease can be made.



ALZHEIMER'S DISEASE: AN UNMET CLINICAL CHALLENGE

Alzheimer's disease is the most common type of dementia¹



One in ten people

65 years of age or older currently has Alzheimer's disease¹

In 2017, an estimated

5.5 million

Americans will have Alzheimer's disease¹

Alzheimer's disease is the

Sixth leading cause of death

in the United States²



5.3 million

65 and older



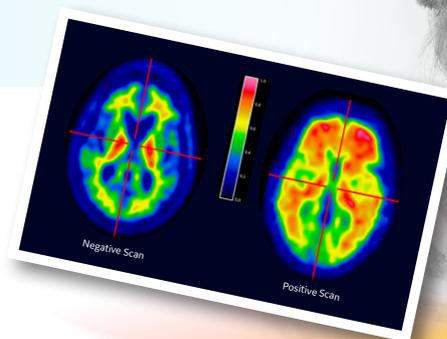
200,000

under 65 with younger-onset Alzheimer's disease

Delayed diagnosis or misdiagnosis of Alzheimer's disease has consequences for patients, caregivers, and healthcare providers²⁻⁵

Vizamyl imaging of the brain can help physicians make the correct dementia diagnosis and get patients on the appropriate treatment.

 **VIZAMYL™**
Flutemetamol F18
Injection



Ask your Doctor about Vizamyl and learn more at www.gevizamyl.com

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You should not take Vizamyl if:

- You are sensitive to polysorbate 80 or any other ingredients of Vizamyl. Your doctor can help you understand what these compounds are

Warnings:

- Vizamyl can cause reactions such as flushing or shortness of breath. Be sure to tell your doctor if you have had reactions to other drugs, especially any that contain polysorbate 80
- Like other radioactive drugs, Vizamyl adds to your lifetime radiation exposure. Long-term radiation exposure is related to increased risk of cancer

The most common side effects of Vizamyl:

- Flushing, increased blood pressure, headache, nausea, or dizziness has occurred in one out of every 50 patients

What you should know about taking Vizamyl with other medications:

- Studies have not been conducted to show which, if any, drugs may interfere with the Vizamyl test results. Be sure to tell your doctor what drugs you are taking so that he or she can decide whether you should stop any of them for a period of time before your Vizamyl test

Always talk with your doctor if you have any questions about PET imaging or Vizamyl. Only doctors who have successfully completed the Vizamyl Electronic Reader Training Program should read Vizamyl images.

References

1. Alzheimer's Association. 2017 Alzheimer's disease facts and figures. www.alz.org/facts/overview.asp. Accessed June 5, 2017.
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3. Buckley JS, Salpeter SR. A risk-benefit assessment of dementia medications: systematic review of the evidence. *Drugs Aging*. 2015;32(6):453-467.
4. Johnson KA, Minoshima S, Bohnen NI, et al. Appropriate use criteria for amyloid PET: a report of the Amyloid Imaging Task Force, the Society of Nuclear Medicine and Molecular Imaging, and the Alzheimer's Association. *Alzheimers Dement*. 2013;5(3):476-490.
5. Hunter CA, Kirson NY, Desai U, Cummings AK, Faries DE, Birnbaum HG. Medical costs of Alzheimer's disease misdiagnosis among US Medicare beneficiaries. *Alzheimers Dement*. 2015;11(8):887-895.

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Vizamyl

Consumer Brief Summary

This information does not take the place of talking to your doctor about your medical condition or your treatment.

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You should not take Vizamyl if:

- You are sensitive to Vizamyl, polysorbate 80 or any other ingredients in Vizamyl. Your doctor can help you understand what these compounds are.

Warnings and Precautions:

- Vizamyl can cause reactions such as flushing or shortness of breath. Be sure to tell your doctor if you have had reactions to other drugs, especially any that contain polysorbate 80.
- Image Interpretation errors (especially false positives) have been observed.
- Like other radioactive drugs, Vizamyl adds to your lifetime radiation exposure. Long-term radiation exposure is related to increased risk of cancer.

The most common side effects of Vizamyl:

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What you should know about taking Vizamyl with other medications:

- Studies have not been conducted to show which, if any, drugs may interfere with the Vizamyl test results. Be sure to tell your doctor what drugs you are taking so that he or she can decide whether you should stop any of them for a period of time before your Vizamyl test.

Before taking Vizamyl, tell your doctor about all of your medical conditions, including if you:

- Are pregnant or plan to become pregnant. It is not known if Vizamyl will harm your unborn baby
- Are breastfeeding or plan to breastfeed. It is not known if Vizamyl passes into your breast milk. Talk with your doctor about the best way to feed your baby if you take Vizamyl

Always talk to your doctor if you have any questions about PET imaging or Vizamyl. Only doctors who have successfully completed the Vizamyl Electronic Reader Training Program should read Vizamyl images.

You are encouraged to report negative side effects to the FDA at 800 FDA 1088 or www.fda.gov/medwatch, or contact GE Healthcare at 800 654 0118 (option 2, then option3).

This is a brief summary of the most important information about Vizamyl. For more information, talk with your doctor.

Please see Important Risk and Safety Information and Full Prescribing Information About Vizamyl at <http://www.gevizamyl.com/us/patients/>

