This information is intended for U.S. consumers only Important Safety Information | Prescribing Information



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What Is Lexiscan?

Lexiscan is a prescription medication used in a cardiac nuclear stress test. It works by increasing blood flow in the <u>coronary arteries</u>. Lexiscan is given by IV in preparation for a <u>myocardial perfusion imaging</u> (MPI) test. This uses a special camera to take pictures of your heart, giving your doctor detailed information about blood flow into your heart.

When Lexiscan may be used

Approximately half of the people undergoing a cardiac stress test are unable to use a treadmill or a stationary bicycle because of medical conditions. Lexiscan may be used when a person is unable to exercise enough to increase blood flow to their heart during a <u>cardiac nuclear stress test</u>. Lexiscan is used to help produce images of the heart for diagnosing CAD. Lexiscan should not be used if you have certain abnormal heart rhythms unless you have a pacemaker. Your doctor will determine if Lexiscan is right for you.

Use

Lexiscan (regadenoson) injection is a prescription drug given through an IV line that increases blood flow through the arteries of the heart during a cardiac nuclear stress test. Lexiscan is given to patients when they are unable to exercise adequately for a stress test.

Important Safety Information
Lexiscan should not be given to patients

How a cardiac nuclear stress test with Lexiscan works

If your doctor recommends a stress test with Lexiscan, it may reassure you to know that it's a noninvasive test, meaning it doesn't involve a surgical procedure.

Here's how it works:

You'll be awake the entire time, and either lying down or sitting up in a chair. Your heart rhythm, blood pressure, and oxygen levels will be monitored during the test.

A catheter (small needle) is placed in a vein in your arm. Lexiscan is injected through the catheter into your bloodstream for about 10 seconds, followed immediately by a saline solution to clear the intravenous (IV) line. Lexiscan dilates the coronary arteries to allow increased blood flow to the heart.

10 to 20 seconds after the saline solution, a small dose of <u>radioactive isotope imaging tracer</u> material is injected into the catheter.

After the tracer is absorbed in your system and distributed in your arteries, a special camera will take detailed pictures of your heart. The pictures will show how well blood flows into your heart and if there are any areas of blockage. While you lie on your back with your arms above your head, the camera will take pictures for about 20 to 40 minutes.

One set of images will be taken when Lexiscan is active in your system, and a second set of images will be taken when you're considered at rest.

Usually a <u>nuclear cardiologist</u> and sometimes a <u>radiologist</u> will review the images with the doctor who ordered the test. When you meet with your doctor, he or she will discuss the test results and the next steps you should take.

To learn more about what happens during a stress test with Lexiscan, read Preparing for a Cardiac Nuclear Stress Test.

Read Lexiscan® (regadenoson) injection Full Prescribing Information

🔀 (PDF - 193 KB)

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Use



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Important Safety Information

- · Lexiscan should not be given to patients who have certain abnormal heart rhythms unless they have a pacemaker.
- Lexiscan can cause serious or fatal cardiac arrest, abnormal heart rhythms or heart attack.
- Allergic reactions can occur after Lexiscan injection.
- Drugs such as Lexiscan may cause an increase or decrease in blood pressure, especially in patients with certain heart and blood vessel disorders.
- Lexiscan can cause breathing difficulties. Before receiving Lexiscan, tell your doctor if you have respiratory diseases, such as COPD (chronic obstructive pulmonary disease) or asthma. Tell your doctor about all medications you use to manage these conditions.
- · Lexiscan can increase the risk of seizures. Before receiving Lexiscan, tell your doctor if you have a history of seizures.
- Lexiscan can cause stroke, which may be a result of an increase or decrease in blood pressure.
- The most common side effects that occurred in clinical trials of Lexiscan were shortness of breath, headache, flushing, chest discomfort or chest pain, dizziness, nausea, abdominal discomfort, a metallic taste in the mouth, and feeling hot. Most common side effects began soon after receiving Lexiscan and went away within 15 minutes except for headache, which resolved in most patients within 30 minutes.
- Avoid consuming any caffeine-containing foods and beverages or medicines containing caffeine, aminophylline or theophylline in the 12 hours before your scheduled heart scan.
- · Ask your doctor if you should stop taking any medications you usually take before the day of the test.
- For women who are nursing, pump and discard breast milk for 10 hours after receiving Lexiscan.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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