

GETTING READY FOR YOUR STRESS TEST



What you should know about your cardiac stress test with Lexiscan® (regadenoson) injection.

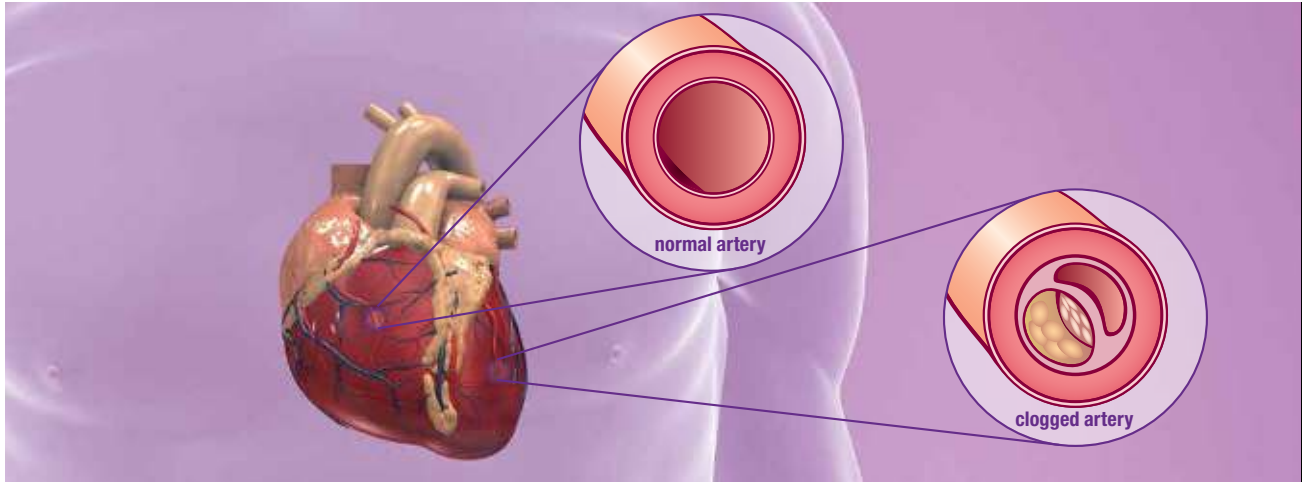


Indication

Lexiscan 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 who have certain abnormal heart rhythms unless they have a pacemaker.

FIGURE 1. NORMAL VS CLOGGED ARTERIES**Important Safety Information (Continued)**

Lexiscan® (regadenoson) injection can cause serious or fatal cardiac arrest, abnormal heart rhythms or heart attack.

Allergic reactions can occur after Lexiscan injection.

What is coronary artery disease?

The heart is a specialized muscle. Like other muscles in your body, it needs oxygen and nutrients. The coronary (heart) arteries deliver oxygen and nutrients to your heart so that it can effectively pump blood throughout your body. People with heart disease may have 1 or more coronary arteries that have become narrowed or clogged over time by fatty deposits (also called plaques). These can decrease blood flow to the heart. See Figure 1 for an illustration that shows you what a normal (healthy) artery looks like compared with a clogged (unhealthy) artery.

So less blood flow is bad, right?

Exactly. Reduced blood flow may cause chest pain (angina), shortness of breath, and potentially a heart attack. Injured heart muscle can be permanently damaged if the coronary arteries stay blocked for too long. If there is a problem with your heart, it is important to find out about it as soon as possible.

My doctor scheduled me for an MPI test. What is it?

MPI stands for myocardial perfusion imaging. The “myocardium” is your heart muscle. “Perfusion” refers to blood flow. And “imaging” is exactly what it sounds like, taking pictures. So, myocardial perfusion imaging is basically taking pictures of the blood flow to your heart. MPI is also called a cardiac nuclear stress test. It is a commonly used test that provides detailed images that can be used to diagnose and assess coronary artery disease.

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Does it hurt?

Except for a small needle (catheter) that will be placed in a vein (IV) in your arm at the start of the test, MPI is a noninvasive test. That means it takes place outside of your body and does not involve surgery of any kind. You will stay awake and alert the entire time.

A small amount of radioactive liquid, called a tracer, will be injected into your bloodstream through the catheter during the MPI test. This tracer helps the doctor see the blood flow to your heart. You probably will not feel any effects from the tracer, which your body eliminates by natural means.

So it's radioactive?

Yes. Remember, radiation is always around us, from computers to wireless technology. Your doctor will make sure this is an appropriate test by looking at the amount of radiation you will be exposed to compared to your risks for heart disease. In many cases, not having this test may present higher risk than having it done.

Okay, how do the pictures work? Is there a camera or something?

Yes. A special camera will take pictures of your heart once the tracer moves through your arteries. Depending on the type of test, you may be required to have 2 sets of pictures taken by the camera at 2 different times (either later that day or even the next). These pictures give doctors detailed information about blood flow into your heart. They might see that some areas of your heart are blocked and not getting all the oxygen and nutrients they need. This information will help your doctors decide what steps should be taken next.

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Important Safety Information (Continued)

Drugs such as Lexiscan® (regadenoson) injection 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.

How will the test be monitored?

Your MPI test will be done under the supervision of your heart imaging team, which may consist of a cardiologist, a certified technologist, a radiologist, and/or a registered nurse. In addition to the catheter, electrocardiograph (ECG) leads will be placed on your upper body, and a blood pressure cuff will be used to check your blood pressure. These are all normal monitoring procedures during the test.

What else happens during an MPI test?

To help the tracer move quickly through your body and to your heart, it is necessary to get more blood flowing to your heart. This can often be achieved by walking briskly on a treadmill. This test is known as “exercise stress.” If for any reason you are not able to exercise on the treadmill for your MPI test, your doctor may prescribe a medication that will be given through the catheter to increase blood flow to your heart.

This procedure is called pharmacologic stress, and it’s used millions of times a year to help produce images.

Really? That seems like a lot.

Well, there are any number of reasons why someone may be unable to exercise adequately for an MPI test. Age, obesity, arthritis, diabetes, and even chronic kidney disease can make exercise difficult. If you are unsure of your exercise capability, your doctor may suggest MPI testing with exercise, then switch to pharmacologic stress if deemed necessary and appropriate.

I see. What’s the drug called?

There are a few different pharmacologic stress agents available, but the most commonly used one is called Lexiscan® (regadenoson) injection.



Important Safety Information (Continued)

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.

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Important Safety Information (Continued)

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.

What exactly does Lexiscan do?

Lexiscan 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.

How will Lexiscan be given?

Well, you may be lying down on a hospital cart or sitting in a chair when you receive Lexiscan. A nurse or other lab professional will inject Lexiscan, and then the tracer, through the catheter that is already in your arm. You'll feel the effects of the Lexiscan almost immediately.

It's important to understand that, whether you exercise on a treadmill or receive Lexiscan stress, the goal is the same: to increase blood flow to your heart so the tracer is completely distributed throughout your heart for imaging.

What are the most common side effects with Lexiscan?

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. You will be monitored before and after administration of Lexiscan for any side effects that require treatment.

Such side effects are expected, so be sure to tell the physician or lab personnel how you're feeling. Remember, these effects usually go away within minutes. After you receive Lexiscan, you'll be ready for the images to be taken between 1-2 hours later.

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What do I need to do during the imaging part of the test?

For the best possible images of your heart, just do your best to relax and stay still. The goal is to be sure you are as comfortable as possible during the procedure. You may still be feeling the effects of Lexiscan® (regadenoson) injection when you're ready for the images to be taken. This is expected.

During the imaging part of the test, you'll rest on your back with your arms above your head. The camera will take images of your heart for about 20 to 40 minutes. It's very important you're comfortable so you can be as still as possible for the camera to produce the best images. The camera is large, but don't worry. It won't touch your body, and it doesn't hurt.

Important Safety Information (Continued)

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.

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You mentioned that there might be 2 sets of images. How does that work?

One set of images will be taken after the treadmill exercise or after you've received pharmacologic stress. You may have another set of images taken while you're at rest. Comparing these 2 sets of images makes it easier for your doctor to see if any parts of your heart are not getting enough blood.

What happens after the test?

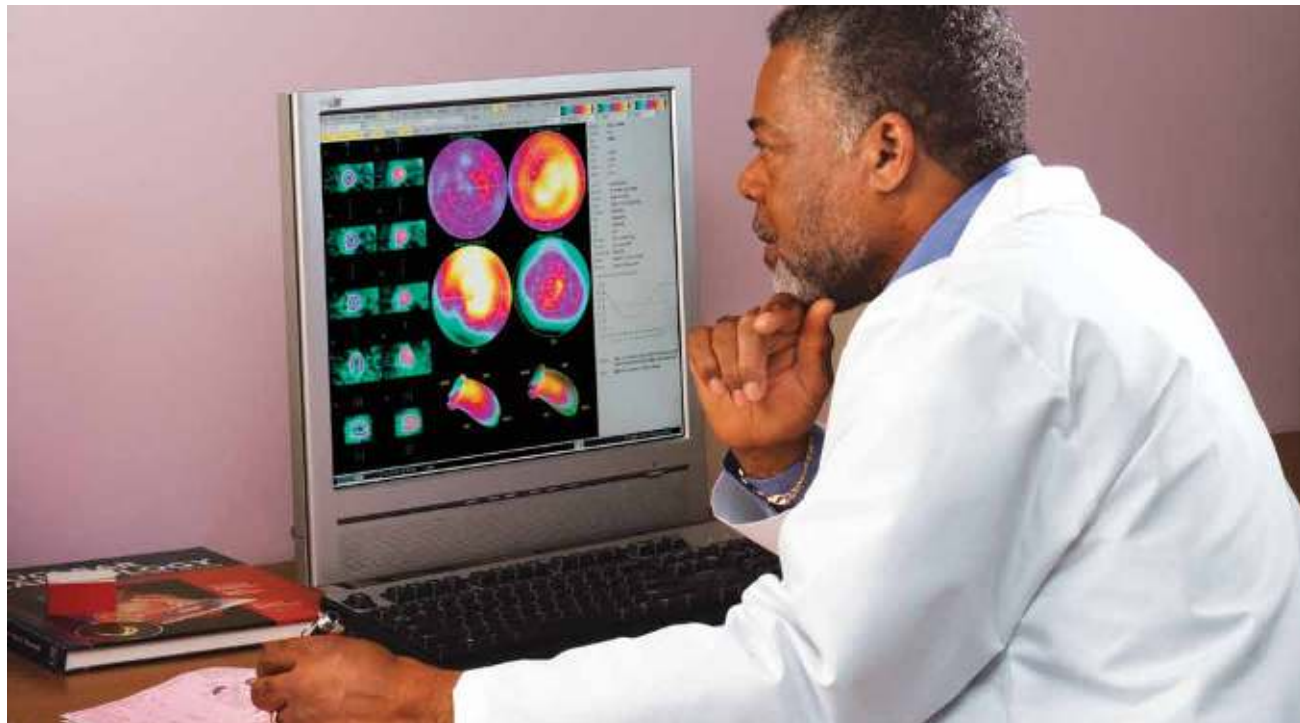
A nuclear cardiologist or radiologist will look at the pictures of your heart to look for areas that might not be getting enough blood. They will discuss the images with the doctor who ordered the test, who may be your cardiologist or your primary care doctor. When you meet with your doctor, you'll discuss the test results and decide what steps to take next. These may include some simple lifestyle changes, new medications, or more testing.

Important Safety Information (Continued)

For women who are nursing, pump and discard breast milk for 10 hours after receiving Lexiscan® (regadenoson) injection.

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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Which foods, drinks, and medications should I avoid before my test?

DO NOT consume caffeine-containing foods and drinks or medications that contain methylxanthines (eg, caffeine, aminophylline, or theophylline) in the 12 hours before your scheduled stress test in the event that pharmacologic stress is used. In addition, avoid any prescription medications containing dipyridamole in the 48 hours before your stress test.

TABLE 1: FOODS TO AVOID

chocolate candies
chocolate cakes
brownies
chocolate pudding
energy bars
foods containing guarana

See Tables 1-3 for a list of some foods, drinks, and drugs to avoid before the test. Remember, it is only a partial list. Your doctor and pharmacist will know about other products, foods, drinks, and medications you shouldn't have before your test. Be sure to tell your doctor which over-the-counter (OTC) and prescription drugs you're currently taking. Your doctor will then give you instructions about those medications.

TABLE 2: DRINKS TO AVOID

chocolate milk
hot cocoa
coffee (brewed, instant, iced, decaf)
tea (brewed, instant, iced, decaf)
soda pop (including "caffeine-free")
energy drinks
drinks containing guarana

TABLE 3: MEDICATIONS TO AVOID		
OTC drugs containing caffeine	Prescription drugs containing caffeine	
Anacin® (aspirin, caffeine)	Cafergot® (ergotamine tartrate, caffeine)	Prescription drugs containing dipyridamole (withhold for 48 hours)
Excedrin® (acetaminophen, aspirin, caffeine)	Esgic® (butalbital, acetaminophen, caffeine)	
Vivarin® (caffeine)	Fioricet® (butalbital, acetaminophen, caffeine)	Persantine® (dipyridamole)
NoDoz® (caffeine)	Fiorinal® (butalbital, aspirin, caffeine)	Prescription drugs containing theophylline
		Elixophylline® (theophylline)
		Theo-24® (theophylline)

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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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We hope this brochure has helped you get a better understanding of your cardiac nuclear stress test with Lexiscan[®] (regadenoson) injection.

For more tips on how to prepare for your test, see page 19, which you can print, fill out, and bring with you on the day of your appointment.

Important Safety Information (Continued)

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**Okay, I think I understand the test.
So what should I do to prepare for it?**

Glad you asked! Be sure to read and understand the following steps to take **BEFORE** the day of your test:

- Ask your doctor if you should follow any dietary restrictions before your test
- Ask your doctor if you should stop taking any medications you usually take before the day of the test
- If you have diabetes and use insulin or oral diabetes medications, ask your doctor for special instructions
- Tell your doctor if you have a history of wheezing, asthma, or chronic lung disease
- Tell your doctor if you have a history of seizures

- Methylxanthines interfere with the activity of pharmacologic stress agents. **DO NOT** consume foods, drinks, or medications that contain methylxanthines (eg, caffeine, aminophylline, or theophylline) for **at least 12 hours before the test in the event that a pharmacologic stress agent will be administered**; one easy way to remember this is:

“12 hours or less, no pharm stress.”

Some medications containing certain ingredients should also be avoided; see the tables on pages 14 and 15 for products you should avoid

- **DO NOT** apply creams, lotions, or powder to your chest area on the day of the test
- Wear comfortable clothing and shoes



CAFFEINE REMINDER!
12 hours or less, no pharm stress.