

## An Axumin scan can detect and localize recurrent prostate cancer

**Axumin is an FDA-approved diagnostic imaging agent, also known as a “tracer,” which may help your physician determine if and where your prostate cancer has returned.**

Like many imaging tracers, Axumin includes a radioactive element (fluorine 18) which is used to produce images of your body and its internal organs and tissues. Over time and through a natural process, the fluorine 18 will become non-radioactive, and much of it will leave your body in your urine.

Detailed information about the extent and location of your disease.

## Axumin is used with a PET/CT scan

**Your Axumin study is done using a PET/CT scanner in a hospital or free-standing imaging facility.**

PET/CT scanning combines two imaging techniques. A positron emission tomography (PET) scan shows physiologic (functional) changes in the body, and a computed tomography (CT) scan shows a detailed depiction of your anatomy, where these changes could be taking place.

Together, these two imaging techniques provide your physician with detailed information about the extent and location of your disease.

### INDICATION

**Axumin® (fluciclovine F 18) injection** is indicated for positron emission tomography (PET) imaging in men with suspected prostate cancer recurrence based on elevated blood prostate specific antigen (PSA) levels following prior treatment.

### IMPORTANT SAFETY INFORMATION

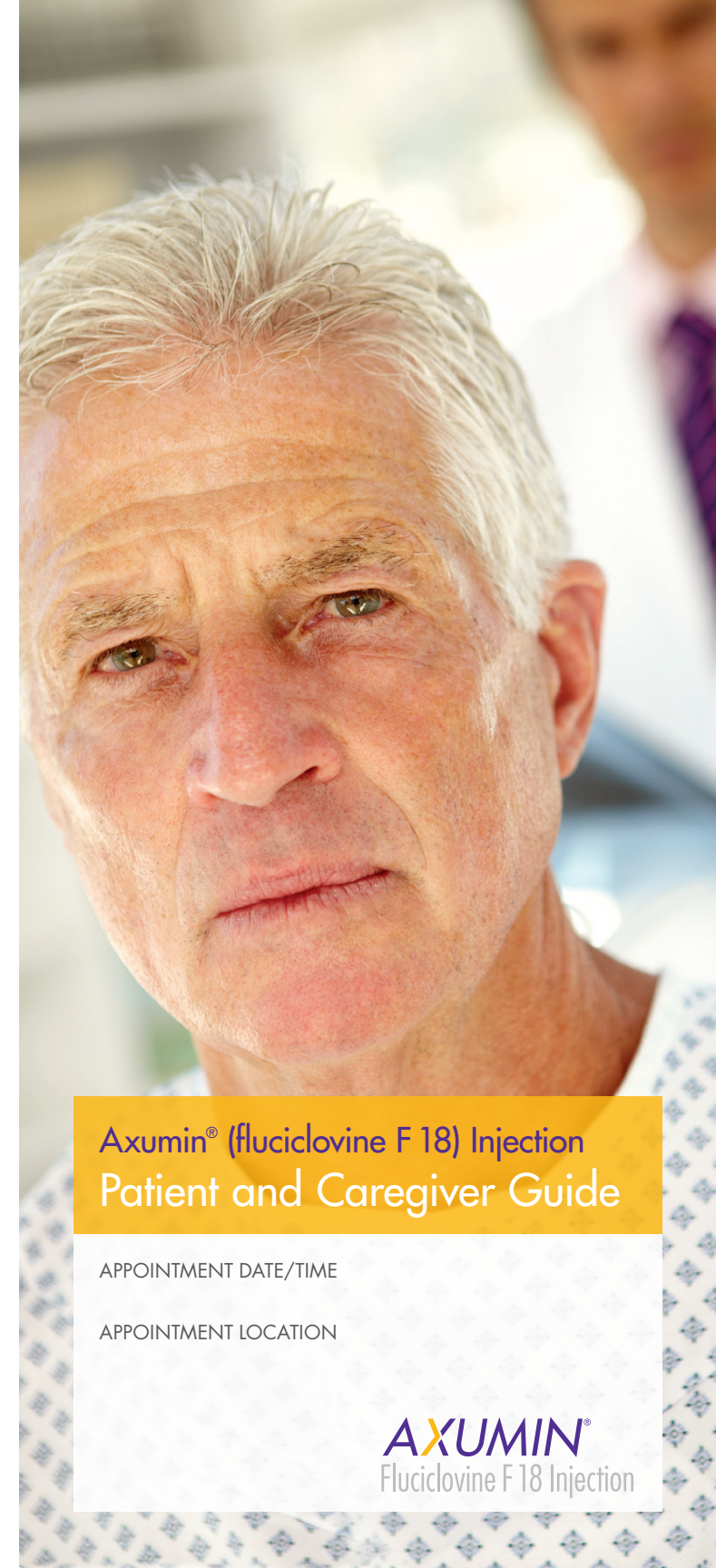
- Image interpretation errors can occur with Axumin PET imaging. A negative image does not rule out recurrent prostate cancer and a positive image does not confirm its presence. The performance of Axumin seems to be affected by PSA levels. Axumin uptake may occur with other cancers and benign prostatic hypertrophy in primary prostate cancer. Clinical correlation, which may include examination of tissue samples, is recommended.
- Severe allergic reactions, including anaphylaxis, may occur in patients who receive Axumin. Emergency resuscitation equipment and personnel should be immediately available.
- Axumin use contributes to a patient’s overall long-term cumulative radiation exposure, which is associated with an increased risk of cancer. Safe handling practices should be used to minimize radiation exposure to the patient and health care providers.
- Adverse reactions were reported in  $\leq 1\%$  of subjects during clinical studies with Axumin. The most common adverse reactions were redness and pain at the injection site, and an unusual taste in the mouth.

To report suspected adverse reactions to Axumin, call **1-855-AXUMINI** (1-855-298-6461) or contact FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

**Please see accompanying full Prescribing Information.**



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## Axumin® (fluciclovine F 18) Injection Patient and Caregiver Guide

APPOINTMENT DATE/TIME

APPOINTMENT LOCATION

**AXUMIN®**  
Fluciclovine F 18 Injection

## Preparing for the Axumin<sup>®</sup> (fluciclovine F 18) injection and scan

24

### 24 hours

Avoid any significant exercise for at least a full 24 hours prior to your Axumin PET/CT scan.

4

### 4 hours

Do not eat or drink for at least 4 hours prior to your PET/CT scan (other than small amounts of water for taking medications).

Don't eat or drink for at least 4 hours prior to your PET/CT scan.



PET/CT scan

Image courtesy of Siemens

## What to expect the day of the scan

### Imaging preparation

Once in the imaging room, you may be asked to sit in a chair, or helped onto a PET/CT scanner table while a nurse or technologist inserts an intravenous (IV) line (usually in your arm). Once on the scanner table, you will be asked to lie on your back and put your arms over your head. Please inform a staff member if this will be an uncomfortable position to hold for 30 minutes.

### Axumin injection

Before the Axumin injection, a saline solution (salt water) will be put in your IV to check it has been properly inserted. Axumin will then be administered through your IV. Once Axumin has been given, more saline will be put in the IV to ensure you received the full Axumin dose for your scan. The PET/CT scan will begin approximately 3 to 5 minutes after completion.

### The PET/CT scan

The scan is painless and lasts approximately 30 minutes. If you are experiencing any discomfort, please alert a staff member. During the scan, lie as still as possible on the scanner bed and breathe normally. You will feel the bed move slowly through the PET/CT scanner opening. The nurse or technologist will provide you with any instructions or information throughout this process. In clinical studies evaluating the safety of Axumin, reported side effects were uncommon. These included redness and pain at the injection site, and an unusual taste in the mouth.

Please see **AXUMIN Important Safety Information on back and accompanying full Prescribing Information.**

## Axumin PET/CT results are typically available in a few days

Once the PET/CT scan is complete, the nurse or technologist will assist you off the table, and you will be asked to wait a few minutes while the images are processing.

After your scan, you may receive instructions to take home with you. If you have any questions after the scan, call your physician. You may resume normal activities immediately after the PET/CT scan, unless your physician has instructed otherwise. To help flush any remaining Axumin from your body, drink as much fluid as possible for the remainder of the day and empty your bladder frequently, unless otherwise instructed by your physician.

Results will be reported to your doctor as soon as possible, usually within a few days.

Your scans will be read by an imaging specialist, such as a radiologist or nuclear medicine physician, and the results will be reported to your doctor as soon as possible, usually within a few days.

