

AXUMIN[®]
Fluciclovine F 18 Injection

CONCERNED ABOUT ELEVATED PSA LEVELS?

**Partner with your doctor
in finding your recurrent
prostate cancer**

Learn about Axumin[®]
(fluciclovine F 18) injection



*This is not an actual patient.

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 histopathological evaluation, is recommended.

Please see Important Safety Information and the accompanying Prescribing Information.

Your prostate cancer may be back, but you're not alone

Up to 40% of patients who have been diagnosed and treated for prostate cancer have a recurrence within 5-10 years

Recurrent prostate cancer is when your cancer has come back after you have had treatment like prostate surgery or radiation. It can also come back later after being treated with other medicines, including hormone therapy.

You are part of a team of shared decision makers in your prostate cancer treatment, and it's important to be informed about all available options.

“By learning about my recurrent prostate cancer and talking with my urologist, I can be my own best advocate”

*This is not an actual patient.

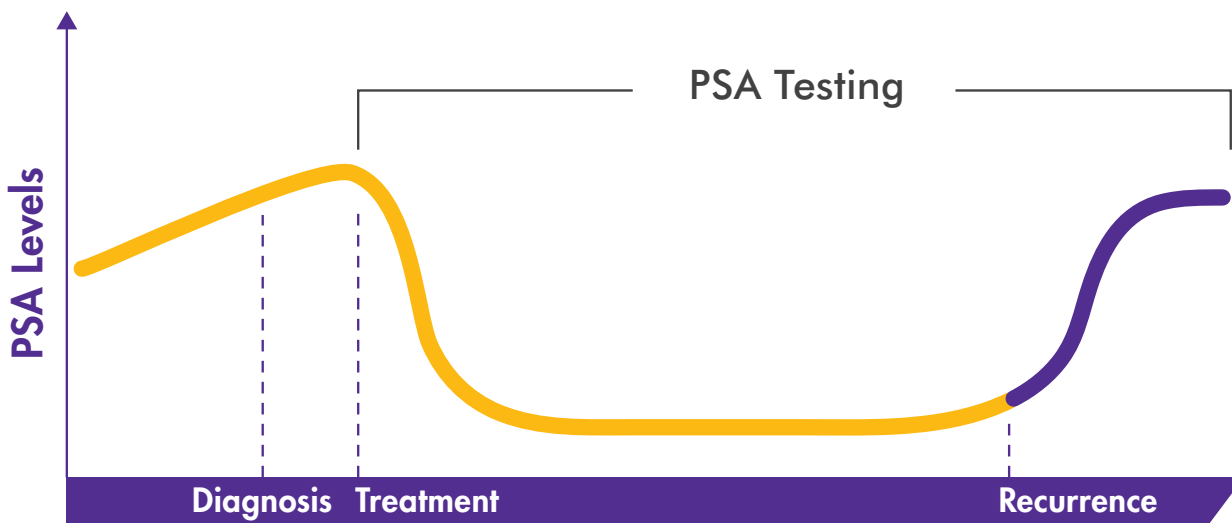
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The meaning of elevated PSA levels

After your initial prostate cancer treatment, you likely had regular checkups with your doctor. These checkups usually include a blood test to monitor your prostate specific antigen, also called PSA.

If your blood test shows your PSA has gone up after surgery, radiation, or hormone therapy, your doctor will likely order another PSA test to confirm the results.



If your PSA is still elevated after these tests, a recurrence of your prostate cancer is indicated. After this, imaging tests may be scheduled to locate where the prostate cancer has returned in your body.

Challenges in locating recurrent prostate cancer

For some patients, recurrent prostate cancer may still be in the prostate if you have had radiation or in the area of the prostate if it has been removed. But the disease can also spread to other parts of the body, including lymph nodes, bones, or other tissues.

It is important to understand exactly where the recurrent prostate cancer is located in your body so that you and your doctor can choose the most appropriate treatment plan for you.

While routine imaging tests including bone scans, CT scans, and MRIs can help provide some information about recurrent prostate cancer, these tests have limitations. There are newer advanced imaging tests available today. Talk to your doctor about which imaging tests are right for you.

“There are limitations with each of the current imaging tests used to locate recurrent prostate cancer”

Imaging tests that help your doctor in their decision making

TYPE	PROS	CONS
Bone scan – looks for different type of bone disease, including cancer	Detects cancer if it's spread to the bone, a common site of recurrence...	But only useful at relatively high PSA levels
CT – creates cross-section images of tissues, bones, and organs	Detects cancer in both bones and soft tissue...	But it may not detect smaller tumors or lesions
MRI – uses magnets and radio waves to create a detailed image	Detects cancer in both bones and soft tissue...	But if you have metal anywhere inside your body, like a pacemaker or artificial joints, you can't have this type of scan

What an Axumin® (fluciclovine F 18) PET/CT scan can tell your doctors

Better detection can lead to more personalized treatment

If you have recurrent prostate cancer, your doctor needs to get more accurate information about the location of your disease.

An Axumin scan may help.

Axumin is an advanced diagnostic imaging agent (sometimes called a radiotracer) used along with a PET/CT scan for men who have had prior treatment for prostate cancer and now have PSA levels that are elevated.



Introducing Axumin

“An Axumin PET/CT scan may help my doctor and me make important treatment decisions”

What to expect when getting an Axumin scan

After the injection, Axumin travels into your cancer cells – including prostate cancer cells – and lights up in the PET/CT scan. An imaging physician will review your scan to find out where the recurrent prostate cancer is located. It is important to note that Axumin may not detect all recurrent prostate cancer, especially at very low PSA levels.



As with all diagnostic imaging tests, it is possible that a physician can interpret your Axumin PET/CT scan results incorrectly. This means that a negative Axumin PET/CT scan does not rule out a prostate cancer recurrence. Similarly, a positive Axumin PET/CT scan does not confirm a prostate cancer recurrence.

See the [accompanying appointment tracker](#) and [Axumin doctor discussion guide](#)

Please see [Important Safety Information](#) and the [accompanying Prescribing Information](#).

AXUMIN[®]
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Making informed decisions through greater knowledge

The more information your doctor has about your recurrent prostate cancer, the more personalized your treatment plan can be.

Ask your doctor if an Axumin[®] (fluciclovine F 18) scan is right for you. Your healthcare team can use the results from the Axumin scan, along with other tests, to help them find your recurrent prostate cancer and create a personalized treatment plan for your cancer.



PET/CT scan
Image courtesy of Siemens Healthineers

*This is not an actual patient.

Please see [Important Safety Information](#) and the [accompanying Prescribing Information](#).

AXUMIN[®]
Fluciclovine F 18 Injection

Preparing for your PET/CT scan with Axumin

Day of the scan

Things to avoid



Avoid any significant exercise in the 24 hours before your Axumin PET/CT scan.



Don't eat or drink anything for 4 hours before your scan.

Preparing for your PET/CT scan

- You'll get an IV of saline (salt water) before your Axumin injection to check if the IV has been properly inserted and after Axumin to make sure you received the full dose
- The scan is painless and lasts 20-30 minutes. You will have to lie as still as possible on the scanner bed, but you can breathe normally. If you feel any discomfort, be sure to tell a staff member immediately
- The bed will move slowly through the PET/CT scanner opening. A nurse or technologist will be there to assist you or provide any additional instructions

In clinical trials that looked at 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.

Fill out this form and bring it with you to your next appointment

Talk With Your Doctor About Axumin[®] (Fluciclovine F 18)

Having an Axumin PET/CT scan can provide you and your doctor with important information about your recurrent prostate cancer.

The following questions and concerns can help guide your conversation with your doctor at your next visit.

Questions about an Axumin scan:

- My PSA levels are rising but my bone scan is negative. Can an Axumin scan tell my doctor where it is coming from?
- Now that my prostate cancer is back, what are my treatment choices?

General discussion topics for your doctor:

- I am interested in a personalized treatment plan.
- I am interested in treating my recurrent prostate cancer aggressively.
- Being healthy for as long as possible is very important to me.
- Avoiding hormone therapy for as long as possible is very important to me.

YOUR SCHEDULED AXUMIN SCAN

Date:

Time:

Imaging center:

Address:

.....

Phone number:

FOLLOW-UP VISIT

Date:

Time:

Things to avoid



Don't eat or drink anything for 4 hours before your scan.



Avoid any significant exercise in the 24 hours before your Axumin PET/CT scan.

Visit www.MyAxuminScan.com for more information.

Please see [Important Safety Information](#) and the [accompanying Prescribing Information](#).

AXUMIN[®]
Fluciclovine F 18 Injection

What is Axumin?

Axumin® (fluciclovine F 18) injection is a diagnostic imaging agent (sometimes called a radiotracer). Axumin is used along with a positron emission tomography (PET) imaging scan for men who have had prior treatment for prostate cancer and now have prostate specific antigen (PSA) levels that are elevated.

IMPORTANT SAFETY INFORMATION

What do I need to know about Axumin?

- As with all diagnostic imaging tests such as x-rays, bone scans and computed tomography (CT) scans, it is possible that the physician (a radiologist or nuclear medicine physician) that reviews your Axumin PET/CT scan can interpret your results incorrectly. This means that a negative Axumin PET/CT scan does not rule out that you have recurrent prostate cancer, and a positive Axumin PET/CT scan does not confirm that you have recurrent prostate cancer.
- How well Axumin works seems to be affected by PSA levels. As PSA levels go up, an Axumin PET/CT scan is better able to identify recurrent prostate cancer.
- Serious reactions including anaphylaxis, a severe, potentially life-threatening allergic reaction may occur in patients who receive Axumin.
- Axumin adds to your long-term overall radiation exposure, which can lead to an increased risk of cancer.

What are the possible side effects of Axumin?

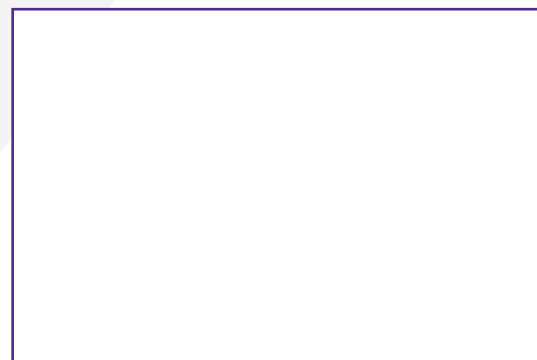
Most commonly reported adverse reactions are:

- Injection site pain
- Injection site redness
- Unusual taste in the mouth

Tell your doctor if you have any side effect that bothers you or does not go away.

These are not all the possible side effects of Axumin. For more information, ask your doctor or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Visit www.MyAxuminScan.com for more information.



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Please see [accompanying Prescribing Information](#).

AXUMIN[®]
Fluciclovine F 18 Injection

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use AXUMIN safely and effectively. See [full prescribing information](#) for AXUMIN.

AXUMIN (fluciclovine F 18) injection, for intravenous use

Initial U.S. Approval: 2016

INDICATIONS AND USAGE

Axumin is a radioactive diagnostic agent 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 (1).

DOSAGE AND ADMINISTRATION

- Use appropriate radiation safety handling measures (2.1).
- Aseptically withdraw Axumin from its container and administer 370 MBq (10 mCi) as a bolus intravenous injection. (2.2).
- Initiate imaging 3-5 minutes after administration. Scanning should start from mid-thigh and proceed to base of skull, with a total scan time of approximately 20-30 minutes (2.4).
- The (radiation absorbed) effective dose associated with 370 MBq (10 mCi) of injected activity of Axumin is approximately 8 mSv (0.8 rem) in an adult (2.6).

DOSAGE FORMS AND STRENGTHS

Injection: clear, colorless solution in a 30 mL multiple-dose vial containing 335-8200 MBq/mL (9-221 mCi/mL) fluciclovine F 18 at calibration time and date (3).

CONTRAINDICATIONS

None (4)

WARNINGS AND PRECAUTIONS

- Image interpretation errors can occur with Axumin imaging (5.1).
- Radiation risk: Axumin contributes to a patient's long-term cumulative radiation exposure. Ensure safe handling to protect patients and health care workers from unintentional radiation exposure (2.1, 5.3).

ADVERSE REACTIONS

Most commonly reported adverse reactions are injection site pain, erythema, and dysgeusia (6.1).

To report SUSPECTED ADVERSE REACTIONS, contact Blue Earth Diagnostics, Ltd at 1-855-AXUMIN1 (1-855-298-6461) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION

Revised: 8/2016

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

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

2 DOSAGE AND ADMINISTRATION

2.1 Radiation Safety - Drug Handling

Axumin is a radioactive drug and should be handled with appropriate safety measures to minimize radiation exposure during administration [see *Warnings and Precautions* (5.3)]. Use waterproof gloves and effective shielding, including syringe shields, when handling and administering Axumin.

2.2 Recommended Dose and Administration Instructions

The recommended dose is 370 MBq (10 mCi) administered as an intravenous bolus injection.

- Inspect Axumin visually for particulate matter and discoloration before administration. Do not use the drug if the solution contains particulate matter or is discolored.
- Use aseptic technique and radiation shielding when withdrawing and administering Axumin.
- Calculate the necessary volume to administer based on calibration time and date, using a suitably calibrated instrument. The recommended maximum volume of injection of undiluted Axumin is 5mL.
- Axumin may be diluted with Sodium Chloride Injection, 0.9%.
- After the Axumin injection, administer an intravenous flush of sterile Sodium Chloride Injection, 0.9% to ensure full delivery of the dose.
- Dispose of any unused drug in a safe manner in compliance with applicable regulations.

2.3 Patient Preparation Prior to PET Imaging

- Advise the patient to avoid any significant exercise for at least one day prior to PET imaging.
- Advise patients not to eat or drink for at least 4 hours (other than small amounts of water for taking medications) prior to administration of Axumin.

2.4 Image Acquisition Guidelines

Position the patient supine with arms above the head. Begin PET scanning 3 to 5 minutes after completion of the Axumin injection. It is recommended that image acquisition should start from mid-thigh and proceed to the base of the skull. Typical total scan time is between 20 to 30 minutes.

2.5 Image Display and Interpretation

Localization of prostate cancer recurrence in sites typical for prostate cancer recurrence is based on fluciclovine F 18 uptake in comparison with tissue background. For small lesions (less than 1cm in diameter) focal uptake greater than blood pool should be considered suspicious for prostate cancer recurrence. For larger lesions, uptake equal to or greater than bone marrow is considered suspicious for prostate cancer recurrence.

2.6 Radiation Dosimetry

The radiation absorbed doses estimated for adult patients following intravenous injection of Axumin are shown in Table 1. Values were calculated from human biodistribution data using OLINDA/EXM (Organ Level Internal Dose Assessment/Exponential Modeling) software.

The (radiation absorbed) effective dose resulting from the administration of the recommended activity of 370 MBq of Axumin is 8 mSv. For an administered activity of 370 MBq (10 mCi), the highest-magnitude radiation doses are delivered to the pancreas, cardiac wall, and uterine wall: 38 mGy, 19 mGy, and 17 mGy, respectively. If a CT scan is simultaneously performed as part of the PET procedure, exposure to ionizing radiation will increase in an amount dependent on the settings used in the CT acquisition.

Table 1: Estimated Radiation Absorbed Doses in Various Organs/Tissues in Adults who Received Axumin

Organ/Tissue	Mean Absorbed Dose per Unit Administered Activity (microGy/MBq)
Adrenal glands	16
Brain	9
Breasts	14
Gallbladder wall	17
Lower large intestine wall	12
Small intestine wall	13
Stomach wall	14
Upper large intestine wall	13
Heart wall	52
Kidneys	14
Liver	33
Lungs	34
Muscle	11
Ovaries	13
Pancreas	102
Red bone marrow	25
Osteogenic cells	23
Skin	8
Spleen	24
Testes	17
Thymus gland	12
Thyroid	10
Urinary bladder wall	25
Uterus	45
Total body	13
Effective dose	22 (microSv/MBq)

3 DOSAGE FORMS AND STRENGTHS

Injection: supplied as a clear, colorless solution in a 30 mL multiple-dose vial containing 335 to 8200 MBq/mL (9 to 221 mCi/mL) fluciclovine F 18 at calibration time and date.

4 CONTRAINDICATIONS

None

5 WARNINGS AND PRECAUTIONS

5.1 Risk for Image Misinterpretation

Image interpretation errors can occur with Axumin PET imaging. A negative image does not rule out the presence of recurrent prostate cancer and a positive image does not confirm the presence of recurrent prostate cancer. The performance of Axumin seems to be affected by PSA levels [*See Clinical Studies (14)*]. Fluciclovine F 18 uptake is not specific for prostate cancer and may occur with other types of cancer and benign prostatic hypertrophy in primary prostate cancer. Clinical correlation, which may include histopathological evaluation of the suspected recurrence site, is recommended.

5.2 Hypersensitivity Reactions

Hypersensitivity reactions including anaphylaxis may occur in patients who receive Axumin. Emergency resuscitation equipment and personnel should be immediately available.

5.3 Radiation Risks

Axumin use contributes to a patient's overall long-term cumulative radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk for cancer. Ensure safe handling to minimize radiation exposure to the patient and health care providers [*see Dosage and Administration (2.1)*].

6 ADVERSE REACTIONS

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. The clinical trial database for Axumin includes data from 877 subjects including 797 males diagnosed with prostate cancer. Most patients received a single administration of Axumin, a small number of subjects (n = 50) received up to five administrations of the drug. The mean administered activity was 370 MBq (range, 163 to 485 MBq).

Adverse reactions were reported in $\leq 1\%$ of subjects during clinical studies with Axumin. The most common adverse reactions were injection site pain, injection site erythema and dysgeusia.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Axumin is not indicated for use in females and there is no information on the risk of adverse development outcomes in pregnant women or animals with the use of fluciclovine F 18.

8.2 Lactation

Risk Summary

Axumin is not indicated for use in females and there is no information of the presence of fluciclovine F 18 in human milk.

8.3 Pediatric Use

Safety and effectiveness have not been established in pediatric patients.

8.4 Geriatric Use

Of the total number of patients in clinical studies of Axumin, the average age was 66 years with a range of 21 to 90 years. No overall differences in safety or effectiveness were observed between older subjects and younger subjects.

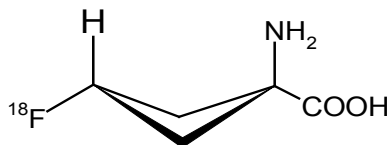
10 OVERDOSAGE

In case of overdose of Axumin, encourage patients to maintain hydration and to void frequently to minimize radiation exposure.

11 DESCRIPTION

11.1 Chemical Characteristics

Axumin contains the fluorine 18 (F 18) labeled synthetic amino acid analog fluciclovine. Fluciclovine F 18 is a radioactive diagnostic agent used with PET imaging. Chemically, fluciclovine F 18 is (1r, 3r)-1-amino-3[¹⁸F]fluorocyclobutane-1-carboxylic acid. The molecular weight is 132.1 and the structural formula is:



Axumin is a sterile, non-pyrogenic, clear, colorless, hyperosmolal (approximately 500 - 540 mOsm/kg) injection for intravenous use. Each milliliter contains up to 2 micrograms of fluciclovine, 335 to 8200 MBq (9 to 221 mCi) fluciclovine F 18 at calibration time and date, and 20 mg trisodium citrate in water for injection. The solution also contains hydrochloric acid, sodium hydroxide and has a pH between 4 and 6.

11.2 Physical Characteristics

Fluorine 18 (F 18) is a cyclotron produced radionuclide that decays by positron emission (β^+ decay, 96.7%) and orbital electron capture (3.3%) to stable oxygen 18 with a physical half-life of 109.7 minutes. The positron can undergo annihilation with an electron to produce two gamma rays; the energy of each gamma ray is 511 keV (Table 2).

Table 2: Principal Radiation Produced from Decay of Fluorine 18 Radiation

	Energy (keV)	Abundance (%)
Positron	249.8	96.7
Gamma	511.0	193.5

11.3 External Radiation

The point source air-kerma coefficient for F 18 is 3.75×10^{-17} Gy m²/(Bq s). The first half-value thickness of lead (Pb) for F 18 gamma rays is approximately 6 mm. The relative reduction of radiation emitted by F 18 that results from various thicknesses of lead shielding is shown in Table 3. The use of 8 cm of Pb will decrease the radiation transmission (i.e., exposure) by a factor of about 10,000.

Table 3: Radiation Attenuation of 511 keV Gamma Rays by Lead Shielding

Shield Thickness cm of Lead (Pb)	Coefficient of Attenuation
0.6	0.5
2	0.1
4	0.01
6	0.001
8	0.0001

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of action

Fluciclovine F 18 is a synthetic amino acid transported across mammalian cell membranes by amino acid transporters, such as LAT-1 and ASCT2, which are upregulated in prostate cancer cells. Fluciclovine F 18 is taken up to a greater extent in prostate cancer cells compared with surrounding normal tissues.

12.2 Pharmacodynamics

Following intravenous administration, the tumor-to-normal tissue contrast is highest between 4 and 10 minutes after injection, with a 61% reduction in mean tumor uptake at 90 minutes after injection.

12.3 Pharmacokinetics

Distribution

Following intravenous administration, fluciclovine F 18 distributes to the liver (14% of administered activity), pancreas (3%), lung (7%), red bone marrow (12%) and myocardium (4%). With increasing time, fluciclovine F 18 distributes to skeletal muscle.

Excretion

Across the first four hours post-injection, 3% of administered radioactivity was excreted in the urine. Across the first 24 hours post-injection, 5% of administered radioactivity was excreted in the urine.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

No long term studies in animals have been performed to evaluate the carcinogenic potential of fluciclovine.

Mutagenesis

Fluciclovine was not mutagenic *in vitro* in reverse mutation assay in bacterial cells and in chromosome aberration test in cultured mammalian cells, and was negative in an *in vivo* clastogenicity assay in rats after intravenous injection of doses up to 43 mcg/kg. However, fluciclovine F 18 has the potential to be mutagenic because of the F 18 radioisotope.

Impairment of Fertility

No studies in animals have been performed to evaluate potential impairment of fertility in males or females.

14 CLINICAL STUDIES

The safety and efficacy of Axumin were evaluated in two studies (Study 1 and Study 2) in men with suspected recurrence of prostate cancer based on rising PSA levels following radical prostatectomy and/or radiotherapy.

Study 1 evaluated 105 Axumin scans in comparison to histopathology obtained by biopsy of the prostate bed and biopsies of lesions suspicious by imaging. PET/CT imaging generally included the abdomen and pelvic regions. The Axumin images were originally read by on-site readers. The images were subsequently read by three blinded independent readers. Table 4 shows the performance of Axumin in the detection of recurrence in each patient scan and, specifically, within the prostatic bed and extra-prostatic regions, respectively. The results of the independent read were generally consistent with one another and confirmed the results of the on-site reads.

Table 4: Performance of Axumin in Patients with Biochemically Suspected Recurrent Prostate Cancer, at the Patient Level and at the Prostate Bed and Extraprostatic Region Levels

	Reader 1	Reader 2	Reader 3
Patient	N = 104	N = 105	N = 99
True Positive	75	72	63
False Positive	24	23	13
True Negative	5	7	15
False Negative	0	3	8
Prostate Bed	N = 98	N = 97	N = 96
True Positive	58	56	47
False Positive	29	26	15
True Negative	10	12	24
False Negative	1	3	10
Extraprostatic	N = 28	N = 28	N = 25
True Positive	25	26	22
False Positive	2	2	2
True Negative	0	0	0
False Negative	1	0	1

N = number of patient scans evaluated

The detection rate of Axumin seems to be affected by PSA levels [see *Warnings and Precautions (5.1)*]. In general, patients with negative scans had lower PSA values than those with positive scans. The detection rate (number with positive scans/total scanned) for patients with a PSA value of less than or equal to 1.78 ng/mL (1st PSA quartile) was 15/25, of which 11 were histologically confirmed as positive. In the remaining three PSA quartiles, the detection rate was 71/74, of which 58 were histologically confirmed. Among the 25 patients in the first PSA quartile, there were 4 false positive scans and 1 false negative scan. For the 74 patients with PSA levels greater than 1.78 ng/mL, there were 13 false positive scans and no false negative scans.

Study 2 evaluated the concordance between 96 Axumin and C11 choline scans in patients with median PSA value of 1.44 ng/mL (interquartile range = 0.78 to 2.8 ng/mL). The C 11 choline scans were read by on-site readers. The Axumin scans were read by the same three blinded independent readers used for Study 1. The agreement values between the Axumin and C11 choline reads were 61%, 67% and 77%, respectively.

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

Axumin is supplied as a clear, colorless injection in a 30 mL multiple-dose glass vial containing approximately 26 mL solution of 335-8200 MBq/mL (9-221 mCi/mL) fluciclovine F 18 at calibration time and date.

30 mL sterile multiple-dose vial: NDC 69932-001-30

16.2 Storage and Handling

Store Axumin at controlled room temperature (USP) 20°C to 25°C (68°F to 77°F). Axumin does not contain a preservative. Store Axumin within the original container in radiation shielding.

This preparation is approved for use by persons under license by the Nuclear Regulatory Commission or the relevant regulatory authority of an Agreement State.

17 PATIENT COUNSELING INFORMATION

- Instruct patients to avoid significant exercise for at least a day before the PET scan.
- Instruct patients not to eat or drink for at least 4 hours before the PET scan (other than small amounts of water for taking medications).

Marketed by Blue Earth Diagnostics Ltd. Oxford, UK OX4 4GA

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