Axumin™
(fluciclovine F 18)
Injection
Case Studies

November, 2016
Axumin™ (fluciclovine F 18) Injection

**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.
Axumin™ (fluciclovine F 18) Injection

Important Safety Information

- Image interpretation errors can occur with fluciclovine PET imaging. A negative image does not rule out recurrent prostate cancer and a positive image does not confirm its presence. The performance of fluciclovine seems to be affected by PSA levels. Fluciclovine uptake may occur with other cancers and benign prostatic hypertrophy in primary prostate cancer. Clinical correlation, which may include histopathological evaluation, is recommended.

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

- Fluciclovine 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 ≤1% of subjects during clinical studies with fluciclovine. The most common adverse reactions were injection site pain, injection site erythema and dysgeusia.

- To report suspected adverse reactions to Axumin, call 1-855-AXUMIN1 (1-855-298-6461) or contact FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

- Please see full prescribing information at www.axumin.com.
Important Information

• These case studies are being provided to you as examples of the images and information available following Axumin™ PET/CT imaging in patients with biochemically recurrent prostate cancer.

• The responsibility for the accurate and timely acquisition and interpretation of images using Axumin PET/CT scanning rests with the nuclear medicine physician or radiologist supervising the PET/CT imaging facility.

• These case studies are not intended to substitute for the independent medical judgment of the physician(s) responsible for the individual patient’s management, nor are they a guarantee of any specific clinical results.

• Incidental findings are noted in some of the cases, as examples of potential, unanticipated abnormalities that may be identified during interpretation of Axumin images. The diagnostic efficacy of Axumin for the identification of these incidental abnormalities has not been established and confirmatory testing may be considered appropriate.
## Case 1 - Overview

### Clinical History

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<tr>
<td><strong>Age</strong></td>
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<td><strong>Prior Therapy</strong></td>
<td>Radical prostatectomy and bilateral staging pelvic lymphadenectomy</td>
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<td><strong>PSA</strong></td>
<td>0.41 ng/ml</td>
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<td><strong>Reason for Scan</strong></td>
<td>Suspected recurrent Prostate Cancer</td>
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### Acquisition

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<td><strong>PET/CT</strong></td>
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<td><strong>Reconstruction</strong></td>
<td>VPFX</td>
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</table>

Institution Name: Department of Radiology and Imaging Sciences, Emory University, Atlanta, GA, USA
Case 1

Figure 1: MIP (Click to Play)

Figure 2: Internal iliac/pelvic side wall lymph node.

(PET (Top Left) & PET/CT (Top Right) transaxial and PET/CT (Bottom Left) sagittal and (Bottom Right) coronal)

$LN\ SUV_{bw \ max} = 11.9$

$Marrow\ (L3)\ SUV_{bw \ mean} = 3.4$
Case 1

Figure 3: Adrenal activity - normal variant
(PET/CT transaxial)

Figure 4: Benign lymphoceles
(PET/CT transaxial)

Figure 4: Rectal activity
(PET sagittal)

Figure 5: Benign bilateral inguinal nodes
(PET (Top) transaxial and (Bottom) coronal)
Case 1 - Results

Imaging Results Summary

- Internal iliac/pelvic side wall lymph node
- Incidental findings
  - Benign bilateral inguinal nodes.
  - Benign bilateral lymphoceles.
  - Adrenal activity - normal variant.
  - Rectal activity.

NOTE: This case study is provided as an example of the interpretation and utility of Axumin™ PET/CT imaging results. Axumin is not indicated for directing or changing patient management. Such decisions must be based on the independent medical judgment of the physician(s) responsible for the individual patient’s management.
## Case 2 - Overview

### Clinical History

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<td><strong>Prior Therapy</strong></td>
<td>Radiotherapy (EBRT/IMRT)</td>
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<td><strong>PSA</strong></td>
<td>8 ng/ml</td>
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<td><strong>Prior Imaging</strong></td>
<td>Planar Bone Scan, CE-CT, Pelvic &amp; Prostate MRI</td>
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<td><strong>Reason for Scan</strong></td>
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### Acquisition

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<td>PSF, ToF, 2i21s</td>
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**Institution Name:** Oslo University Hospital HF, Radiumhospitalet, Oslo
Case 2

Figure 1: MIP (Click to Play)

Figure 2: Retroperitoneal malignant nodes (PET coronal)

Figure 3: Retroperitoneal malignant node (PET/CT transaxial)

- LN SUV(bw)$_{\text{max}}$ : 8.3
- LN short axis : 1.2 cm
- Marrow (L3) SUV(bw)$_{\text{mean}}$ : 4.0

Figure 4: Thoracic malignant node (PET/CT transaxial)

- LN SUV(bw)$_{\text{max}}$ : 6.0
- LN short axis : 0.6 cm
- Blood Pool (Aorta) SUV(bw)$_{\text{mean}}$ : 1.4

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Case 2

Figure 6: **Benign appearing right iliac sclerosis**
(PET/CT (Top & Bottom Left) transaxials and CT (Bottom Right) coronal)

Figure 7: **Probable benign mild diffuse midline prostate activity**
(PET (Top) and PET-CT (Bottom) transaxials)
Case 2

Figure 8: **Incidental finding: Right arm vein focal activity**
(PET (Top) and PET-CT (Bottom) transaxials)

Figure 5: **Incidental finding: Left adrenal low density hyperplasia or adenoma**
(PET (Top) and CT (Bottom) transaxials)

- Adrenal SUV(bw)_{max} : 3.5
- Marrow (L3) SUV(bw)_{mean} : 4.0
Case 2 - Results

Imaging Results Summary

- Extensive retroperitoneal malignant nodes extending into thorax
- Probable benign mild diffuse midline prostate activity.
- Incidental:
  - Left adrenal hyperplasia/adenoma
  - Right arm vein focal activity
  - Benign appearing right iliac sclerosis.

Management Plan

- Intended: Curative
- Revised: Palliative

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## Case 3 - Overview

### Clinical History

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<td>PSA</td>
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<td>Gleason</td>
<td>3+4 (biopsy)</td>
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<td>Prior Imaging</td>
<td>Planar bone scan; pelvic &amp; prostate MRI (Extraprostatic region negative)</td>
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### Acquisition

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<th>Parameter</th>
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<td>Reconstruction</td>
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Institution Name: Oslo University Hospital HF, Radiumhospitalet, Oslo
Case 3

Figure 1: MIP (Click to Play)

Figure 2: Prostate (right apex) focal malignant uptake
(PET (Left) coronal & (Bottom Right) transaxial & PET/CT (Top Right) transaxial)

Prostate SUV\(_{\text{bw}}\)\(_{\text{max}}\) : 7.4
Marrow (L3) SUV\(_{\text{bw}}\)\(_{\text{mean}}\) : 3.7
Case 3 - Results

Imaging Results Summary
• Prostate (right apex) focal uptake

Histopathology
• Biopsy positive right apex

Management Plan
• Intended: Curative – salvage brachytherapy
• Revised: (No revision)
• PSA nadir <0.2 ng/ml

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## Case 4 - Overview

### Clinical History

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<td><strong>Gleason</strong></td>
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<td>Bone Marrow MRI, Planar Bone Scan</td>
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<td><strong>Reason for Scan</strong></td>
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### Acquisition

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<td>PSF, ToF, 2i21s</td>
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**Institution Name:** Oslo University Hospital HF, Radiumhospitalet, Oslo
Case 4

Figure 1: MIP (Click to Play)

Figure 2: Bone L3 sclerotic malignant uptake

(PET/CT (Top Left) transaxial & (Bottom Right) coronal & CT (Bottom Right) transaxial)

- L3 focal uptake $SUV_{bw, max} = 7.6$
- Marrow (Normal) $SUV_{bw, mean} = 3.8$
Case 4 - Results

Imaging Results Summary

• Bone L3 sclerotic malignant uptake
• Post-op bladder tracer activity.
• Incidental mucocele left maxillary sinus, right renal cysts.

Follow-up Imaging

• Bone marrow MRI: Positive at L3 & also at T12

Management Plan

• Intended: Palliative Radiotherapy (EBRT/IMRT) to Prostate & Vesicles
• Revised: No revision

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## Case 5 - Overview

### Clinical History

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<td><strong>Primary Stage</strong></td>
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<td><strong>Prior Therapy</strong></td>
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<td><strong>Prior Imaging</strong></td>
<td>Negative MRI (apart from Schwannoma right sacrum); planar bone scan</td>
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### Acquisition

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<td><strong>Reconstruction</strong></td>
<td>PSF, ToF, 2i21s</td>
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</tbody>
</table>

Institution Name: Oslo University Hospital HF, Radiumhospitalet, Oslo
Case 5

Figure 1: MIP (Click to Play)

Figure 2: Left presacral lymph node malignant uptake

(CT (Top Left), PET (Bottom Left) & PET/CT (Top Right) transaxial & PET/CT (Bottom Right) coronal)

Lymph Node SUV\((bw)_{max}\) : 6.7
Marrow (L3) SUV\((bw)_{mean}\) : 3.0
Figure 3: Sclerotic lesions (fluciclovine negative) needing further evaluation (i.e. does not exclude metastases).

(CT (Top) & PET/CT (Bottom) transaxials)
Case 5

Figure 4: Bladder activity
(PET/CT (Top) transaxial & PET/CT (Bottom) sagittal)

Figure 5: Mild benign inguinal nodal activity.
(PET (Top) & PET/CT (Bottom) transaxials)
Case 5 - Results

Imaging Results Summary
- Intense small left presacral node (3x4 mm)
- Sclerotic lesions (fluciclovine negative) needing evaluation (i.e. does not exclude metastases).
- Mild symmetric inguinal nodal activity.
- Incidental:
  - Benign left lymphocele.
  - Sinus disease.
  - Bladder activity.

Management Plan
- Intended: Curative - Radiotherapy
- Revised: Palliative - ADT

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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

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