

Axumin™ (fluciclovine F 18) Injection Dosing and Administration

August 2016

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 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 <http://www.fda.gov/medwatch>.

Please note this document provides a summary of patient preparation, dose administration, and image acquisition. Please see full prescribing information, specifically Section 2, for additional details on dosage and administration.

PATIENT PREPARATION

- Advise the patient to avoid any significant exercise for at least one day prior to PET imaging.
 - *If the patient has not avoided exercise, the biodistribution may be altered and this should be taken into account during image interpretation.*
- 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.
 - *If the patient has not fasted, the biodistribution may be altered and this should be taken into account during image interpretation.*
- Patients should be encouraged to void before starting the scanning procedure

DOSE ADMINISTRATION

- Administer the dose as an intravenous bolus injection while the patient is positioned in the PET/CT scanner
 - The recommended dose is 370 MBq (10 mCi)
 - » *Injection into the right arm is preferred as stasis in the left axillary vein may be misinterpreted as a metastatic lymph node (Virchow's node). If the right arm cannot be used, beware of the possibility of image interpretation error.*
- 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.

IMAGE ACQUISITION

- Position the patient supine with arms above the head.
 - *If the patient cannot tolerate this position for the duration of the study, an alternate position for the patient's arms may be used.*
 - High quality CT acquisition for anatomic correlation and attenuation correction is recommended.

AXUMIN™

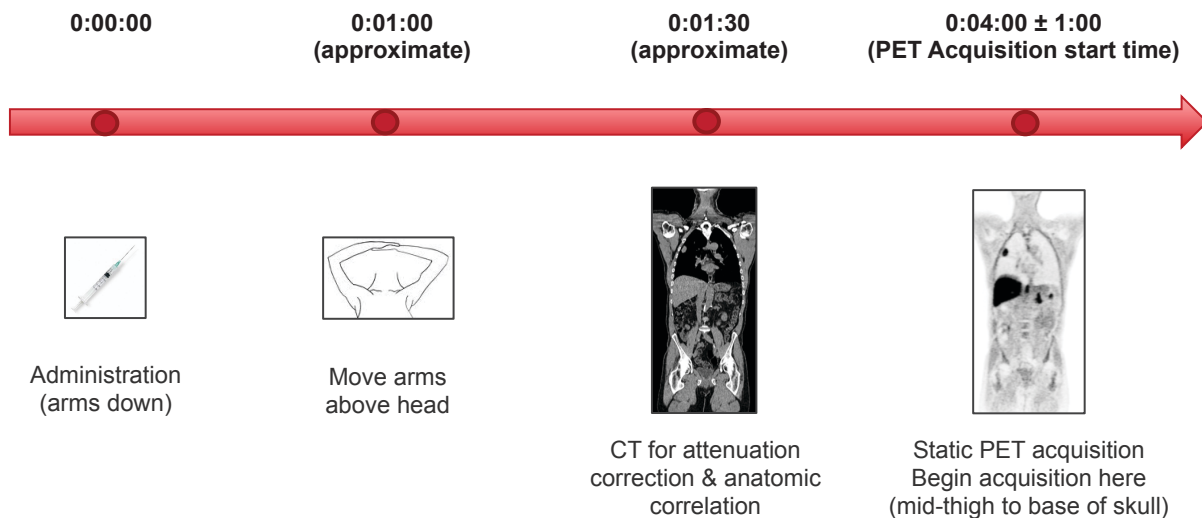
Fluciclovine F 18 Injection

- Begin PET scanning 3 to 5 minutes after completion of the Axumin injection.
 - 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.
 - » *If scanning is started early, the biodistribution may be altered (eg, increased blood pool) and this should be taken into account during image interpretation.*
 - » *If scanning is started late, the biodistribution may be altered (eg, increased muscle uptake) and this should be taken into account during image interpretation.*

Axumin™ (fluciclovine F 18) Injection US Prescribing Information, Blue Earth Diagnostics, Ltd; May 2016

AXUMIN: ACQUISITION

Units: Time to injection (hr:min:sec)



FOR MORE INFORMATION

- Call Medical Information at 1-855 AXUMIN1 (1-855-298-6461); option #3
- Visit: <http://www.Axumin.com>