EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 March 2017
EMA/CHMP/144418/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Axumin

fluciclovine (^{18}F)

On 23 March 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Axumin, intended to be used as a diagnostic agent for the detection of recurrence of prostate cancer with Positron Emission Tomography (PET) imaging. The applicant for this medicinal product is Blue Earth Diagnostics Ltd.

Axumin will be available as a solution for injection (1600 MBq/ml and 3200 MBq/ml). The active substance of Axumin is fluciclovine (^{18}F), a radiopharmaceutical for tumour detection (ATC code: V09IX12). Fluciclovine (^{18}F) is a synthetic amino acid which is transported across mammalian cell membranes by amino acid transporters that are known to be upregulated in prostate cancer, providing a mechanism for the enhanced accumulation of fluciclovine (^{18}F) in prostate cancer.

The benefits with Axumin are its ability to assess with high sensitivity the sites where prostate cancer has reappeared in patients after primary curative treatment of the prostate gland. Axumin is indicated in patients presenting with elevated blood prostate specific antigen (PSA). The most common side effects are dysgeusia, parosmia and injection site reaction.

The full indication is: “This medicinal product is for diagnostic use only. Axumin is indicated for Positron Emission Tomography (PET) imaging to detect recurrence of prostate cancer in adult men with a suspected recurrence based on elevated blood prostate specific antigen (PSA) levels after primary curative treatment.” It is proposed that Axumin be administered by appropriately qualified healthcare professionals. Images should only be interpreted by readers trained in the interpretation of PET images with fluciclovine (^{18}F).

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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