20 March 2014
EMA/CHMP/139150/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Neocepri

folic acid

On 20 March 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional marketing authorisation[2] for the medicinal product Neocepri to be used in patients with ovarian cancer to enhance the image quality of ^{99m}Tc-etarfolatide single photon emission computed tomography (SPECT).

Neocepri was designated an orphan medicinal product on 10 September 2012. The applicant for this medicinal product is Endocyte Europe, B.V.

Neocepri is to be available as a 1 mg/ml solution for injection. The active substance of Neocepri is folic acid to be administered intravenously prior ^{99m}Tc-etarfolatide SPECT imaging (see Summary of opinion on Folcepri).

The benefits with Neocepri are its ability to reduce the background (i.e. non-specific) activity observed on SPECT imaging in most normal, non-target tissues including in the intestines, liver, kidney, and spleen, thereby improving the image quality of the scans.

A pharmacovigilance plan for Neocepri will be implemented as part of the marketing authorisation.

The text of the approved indication is as follows: "This medicinal product is for diagnostic use only. Neocepri is administered prior to ^{99m}Tc-etarfolatide, a folate receptor (FR) targeted radiodiagnostic imaging agent for use in ovarian cancer. Neocepri is indicated for the enhancement of ^{99m}Tc-etarfolatide single photon emission computed tomography (SPECT) image quality."

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.
[2] A conditional marketing authorisation is granted to a medicinal product that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. The marketing authorisation holder is likely to provide comprehensive clinical data at a later stage.

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