20 September 2018
EMA/CHMP/474774/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Apealea

paclitaxel

On 20 September 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Apealea, intended for the treatment of ovarian cancer. The applicant for this medicinal product is Oasmia Pharmaceutical AB.

Apealea will be available as a 60 mg powder for solution for infusion. The active substance of Apealea is paclitaxel, an antineoplastic agent that belongs to the class known as 'taxanes' (ATC code: L01CD01). Paclitaxel blocks a stage of cell division in which the cell's internal 'skeleton' is dismantled to allow the cell to divide. By keeping this structure intact the cells cannot divide and they eventually die. Apealea also affects non-cancer cells such as blood and nerve cells, which can cause side effects.

The benefit with Apealea is its ability to improve progression-free survival in combination with carboplatin. The most common side effects are neutropenia, gastrointestinal disorders, peripheral neuropathy, arthralgia/myalgia, and infusion site reactions.

The full indication is:

"Apealea in combination with carboplatin is indicated for the treatment of adult patients with first relapse of platinum-sensitive epithelial ovarian cancer, primary peritoneal cancer and fallopian tube cancer (see section 5.1)."

It is proposed that Apealea be prescribed by physicians experienced in the use of anticancer therapies.

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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