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Apealea (*paclitaxel*)

An overview of Apealea and why it is authorised in the EU

What is Apealea and what is it used for?

Apealea is a cancer medicine used to treat women with cancer of the ovary or surrounding structures (the fallopian tube that connects the ovary to the womb, or the peritoneum, the membrane that lines the abdomen).

Apealea is given along with a platinum-based medicine, carboplatin, to patients whose disease responds to platinum-based cancer medicines and has come back after initial treatment.

Apealea contains the active substance paclitaxel.

How is Apealea used?

Apealea is available as a powder to make up a solution for infusion (drip) into a vein. The paclitaxel in Apealea is formulated in tiny particles, called micelles, to help it dissolve in the infusion solvent. It should not be interchanged with other medicines containing paclitaxel.

The medicine can only be obtained with a prescription and should be given under the supervision of a specialist in the treatment of cancer.

The dose of Apealea is 250 mg per square metre (calculated based on height and body weight) and is given by infusion over about 1 hour, once every 3 weeks, for 6 cycles of treatment. Doses may be delayed or reduced by the doctor, or treatment may be stopped, if severe side effects occur; doses should also be reduced in patients with moderate or severe reduction in liver function. Patients are also treated with a platinum-based medicine, carboplatin.

For more information about using Apealea, see the package leaflet or contact your doctor or pharmacist.

How does Apealea work?

The active substance in Apealea, paclitaxel, is a cancer medicine that has been used in the EU for many years. It belongs to the group of cancer medicines known as the 'taxanes'. Paclitaxel blocks a

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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.

What benefits of Apealea have been shown in studies?

Apealea has been shown to be as effective as a conventional formulation of paclitaxel in one main study involving further treatment of 789 women whose ovarian, fallopian tube or peritoneal cancer had come back. Patients also received a platinum-based cancer medicine, carboplatin. The average length of time that patients lived without their disease coming back yet again was 10.3 months with Apealea, and 10.1 months with conventional paclitaxel.

Supportive data from the study showed that the average time that patients lived after treatment was 25.7 months among those given Apealea and 24.8 months for those given conventional paclitaxel.

What are the risks associated with Apealea?

The most common side effects with Apealea (which may affect more than 1 in 10 people) are neutropenia (low numbers of white blood cells called neutrophils), stomach and gut disorders such as diarrhoea, nausea (feeling sick) and vomiting, peripheral neuropathy (nerve damage in hands and feet), joint and muscle pain, and reactions such as redness, soreness and inflammation of the veins at the site of infusion. For the full list of side effects of Apealea, see the package leaflet.

Apealea must not be used in patients who are breast feeding or those who already have low levels of neutrophils in the blood. For the full list of restrictions, see the package leaflet.

Why is Apealea authorised in the EU?

The European Medicines Agency considered that Apealea was as effective as conventional paclitaxel, and could be a valuable alternative in combination with carboplatin. While the new formulation might be associated with more infusion site reactions, and studies suggested stronger effects on blood cells and the gut, these were considered manageable and the overall benefits and risks are consistent with those of other paclitaxel medicines. The Agency therefore decided that Apealea's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Apealea?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Apealea have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Apealea are continuously monitored. Side effects reported with Apealea are carefully evaluated and any necessary action taken to protect patients.

Other information about Apealea

Apealea received a marketing authorisation valid throughout the EU on 20 November 2018.

Further information on Apealea can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/apealea.

This overview was last updated in 11-2018.