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EPAR summary for the public

Halaven

eribulin

This is a summary of the European public assessment report (EPAR) for Halaven. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Halaven.

What is Halaven?

Halaven is a cancer medicine that contains the active substance eribulin. It is available as a solution for injection.

What is Halaven used for?

Halaven is used to treat locally advanced or metastatic breast cancer which has continued to spread after at least one previous treatment for advanced cancer. Previous treatment should have included cancer medicines of the types known as anthracyclines and taxanes, unless these treatments were not suitable. 'Metastatic' means that the cancer has spread to other parts of the body.

Halaven is also used to treat adults with advanced or metastatic liposarcoma (a type of cancer of the soft tissues that develops from fat cells) that cannot be surgically removed. It is used in patients who have already been treated with anthracyclines (unless this treatment was not suitable).

The medicine can only be obtained with a prescription.

How is Halaven used?

Halaven treatment should be given under the supervision of a doctor experienced in the use of cancer medicines.

Halaven is given as intravenous (into a vein) injections over 21-day cycles. The dose to be given is calculated using the patient's height and weight. The calculated dose is given into a vein over two to

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five minutes on days 1 and 8 of each cycle. Doctors should consider giving patients an antiemetic (a medicine that prevents nausea and vomiting) as Halaven may cause nausea or vomiting.

Doses may be delayed or reduced if patients have very low levels of neutrophils (a type of white blood cell) and platelets (components that help the blood to clot) in their blood or if liver or kidney function is impaired. For more details on the use of Halaven including recommendations on dose reduction, see the summary of product characteristics (also part of the EPAR).

How does Halaven work?

The active substance in Halaven, eribulin, is similar to an anticancer substance called halichondrin B, which is found in the marine sponge *Halichondria okadai*. It attaches to a protein in cells called tubulin, which is important in the formation of the internal 'skeleton' that cells need to assemble when they divide. By attaching to tubulin in cancer cells, eribulin disrupts the formation of the skeleton, preventing the division and spread of the cancer cells.

How has Halaven been studied?

In breast cancer, Halaven was studied in two main studies involving a total of 1,864 patients. In the first study, Halaven was compared with other treatments in 762 women with advanced or metastatic breast cancer, who had previously undergone at least two other treatments, which included an anthracycline and a taxane. The women were given either Halaven or another approved cancer medicine chosen by their doctor. The main measure of effectiveness was overall survival (how long the patients lived).

The second study involved 1,102 patients with advanced or metastatic breast cancer, with one or two previous treatments for advanced/metastatic cancer including an anthracycline and a taxane. The study compared Halaven with capecitabine (another cancer medicine). The main measures of effectiveness were overall survival and progression-free survival (how long the patients lived without their disease getting worse).

Halaven was also studied in 143 patients with liposarcoma who had previously undergone at least two other treatments, which included an anthracycline. Halaven was compared with dacarbazine (another cancer medicine), and the main measure of effectiveness was overall survival.

What benefit has Halaven shown during the studies?

In the first study, when comparing Halaven with all the other treatments grouped together, Halaven was shown to be more effective at prolonging life. Women in the Halaven group lived for an average of 13.1 months, compared with 10.6 months in the group that received other treatments.

In the second study, there was no significant difference in the average progression-free survival with Halaven (4.1 months) compared with capecitabine (4.2 months) or in the average overall survival with Halaven (15.9 months) compared with capecitabine (14.5 months).

The third study showed that Halaven was effective at prolonging life in patients with liposarcoma: patients treated with Halaven lived for an average of 15.6 months, compared with 8.4 months for patients treated with dacarbazine.

What is the risk associated with Halaven?

The most common side effects with Halaven (seen in more than 1 patient in 10) are neutropenia (low levels of neutrophils, a type of white blood cell that fights infection), leucopenia (low white blood cell counts), anaemia (low red blood cell counts), reduced appetite, peripheral neuropathy (damage to the nerves in the extremities causing numbness, tingling and prickling sensations), headache, dyspnoea (difficulty breathing), cough, nausea (feeling sick), constipation, diarrhoea, vomiting, alopecia (hair loss), muscle and joint pain or pain in the back or limbs, fatigue (tiredness), pyrexia (fever) and weight loss. For the full list of all side effects reported with Halaven, see the package leaflet.

Halaven must not be used in women who are breastfeeding. For the full list of restrictions, see the package leaflet.

Why has Halaven been approved?

The CHMP noted that, when Halaven was used as a third-line therapy for breast cancer (after at least two previous treatments with cancer medicines for advanced/metastatic disease), it prolonged the length of time that patients lived and the safety profile is within what is expected for chemotherapy medicines. When Halaven was used as breast cancer second-line therapy (after at least one previous cancer treatment for advanced/metastatic disease), Halaven was a valuable treatment option similar to capecitabine and with an acceptable safety profile. Additionally, Halaven prolonged the length of time that liposarcoma patients lived, and this was considered important as these patients have limited treatment options. Safety in this patient population was considered acceptable and similar to that in patients with breast cancer.

The CHMP decided that Halaven's benefits are greater than its risks and recommended that it be given marketing authorisation.

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

A risk management plan has been developed to ensure that Halaven is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Halaven, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Halaven

The European Commission granted a marketing authorisation valid throughout the European Union for Halaven on 17 March 2011.

The full EPAR for Halaven can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Halaven, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 05-2016.