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Eribulin Baxter (*eribulin*)

An overview of Eribulin Baxter and why it is authorised in the EU

What is Eribulin Baxter and what is it used for?

Eribulin Baxter is a cancer medicine 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.

Eribulin Baxter 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).

Eribulin Baxter contains the active substance eribulin and is a 'generic medicine'. This means that Eribulin Baxter contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU. The reference medicine for Eribulin Baxter is Halaven. For more information on generic medicines, see the question-and-answer document here.

How is Eribulin Baxter used?

Eribulin Baxter can only be obtained with a prescription and treatment should be given under the supervision of a doctor experienced in the use of cancer medicines.

Eribulin Baxter 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 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 Eribulin Baxter 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 information about using Eribulin Baxter, see the package leaflet or contact your doctor or pharmacist.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

How does Eribulin Baxter work?

The active substance in Eribulin Baxter, 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 Eribulin Baxter been studied?

Studies on the benefits and risks of the active substance in the authorised uses have already been carried out with the reference medicine, Halaven, and do not need to be repeated for Eribulin Baxter.

As for every medicine, the company provided studies on the quality of Eribulin Baxter. There was no need for 'bioequivalence' studies to investigate whether Eribulin Baxter is absorbed similarly to the reference medicine to produce the same level of the active substance in the blood. This is because Eribulin Baxter is given by injection into a vein, so the active substance is delivered straight into the bloodstream.

What are the benefits and risks of Eribulin Baxter?

Because Eribulin Baxter is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Eribulin Baxter authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Eribulin Baxter has been shown to have comparable quality and to be bioequivalent to Halaven. Therefore, the Agency's view was that, as for Halaven, the benefits of Eribulin Baxter outweigh the identified risks and it can be authorised for use in the EU.

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

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

Any additional measures in place for Halaven also apply to Eribulin Baxter where appropriate.

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

Other information about Eribulin Baxter

Eribulin Baxter received a marketing authorisation valid throughout the EU on 27 June 2024.

Further information on Eribulin can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/eribulin-baxter. Information on the reference medicine can also be found on the Agency's website. More information about Halaven can be found in the national registers of relevant Member States.

This overview was last updated in 06 2024.