25 April 2024
EMA/132945/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Eribulin Baxter

eribulin

On 25 April 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Eribulin Baxter, intended for the treatment of adults with locally advanced or metastatic breast cancer and adults with unresectable, advanced or metastatic, liposarcoma.

The applicant for this medicinal product is Baxter Holding B.V.

Eribulin Baxter will be available as a 0.44 mg/ml solution for injection. The active substance of Eribulin Baxter is eribulin, an antineoplastic agent (ATC code: L01XX41). Eribulin inhibits the growth phase of microtubules without affecting the shortening phase. It also sequesters tubulin into non-productive aggregates, preventing microtubule assembly. By disrupting mitotic spindles, eribulin blocks the cell cycle in the G_2/M stage, leading to apoptotic cell death.

Eribulin Baxter is a generic of Halaven, which has been authorised in the EU since 17 March 2011. Since Eribulin Baxter is administered intravenously and is 100% bioavailable, a bioequivalence study versus the reference product Halaven was not required. A question and answer document on generic medicines can be found here.

The full indication is:

> Eribulin Baxter is indicated for the treatment of adult patients with locally advanced or metastatic breast cancer who have progressed after at least one chemotherapeutic regimen for advanced disease (see section 5.1). Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting unless patients were not suitable for these treatments.
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> Eribulin Baxter is indicated for the treatment of adult patients with unresectable liposarcoma who have received prior anthracycline containing therapy (unless unsuitable) for advanced or metastatic disease (see section 5.1).

Eribulin Baxter should be prescribed by physicians experienced in the appropriate use of anti-cancer

[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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therapy.

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.