16 February 2012
EMA/105039/2012
EMEA/H/C/002084

Questions and answers on the expression of the strength for Halaven (eribulin)

The Agency's Committee for Medicinal Products for Human Use (CHMP) has agreed that a letter should be sent to healthcare professionals in the EU to clarify the way the strength of this medicine is expressed in the product information. This is expected to avoid misunderstanding and ensure that patients are given the correct dose.

What is Halaven?

Halaven is an anticancer medicine that contains the active substance eribulin. Halaven is used to treat breast cancer that is advanced or that has spread to other parts of the body. Halaven has been authorised in the European Union since March 2011 and is marketed in the following EU countries: Austria, Denmark, Finland, France, Germany, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden and the United Kingdom.

What is the concern with Halaven?

Halaven contains eribulin in the form of a salt called 'eribulin mesilate', which releases the active substance, eribulin. The strength of Halaven is expressed in the product information in terms of the active substance, eribulin, in line with EU guidelines. However, the strength of Halaven is often expressed in terms of the salt in the scientific literature as well as in the prescribing information used in some countries, including the United States of America (USA).

The Agency is concerned that the expression of strength in the EU product information could be misunderstood by healthcare professionals to be referring to 'eribulin mesilate' rather than to eribulin, which could potentially lead to the wrong dose being given to patients.

What action is being taken?

The CHMP has agreed that a letter should be sent to healthcare professionals in the EU reminding them that the EU product information expresses the strength in terms of the active substance and not in terms of the salt. This is expected to avoid misunderstanding and ensure that patients are given the correct dose.

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As for all medicines, the Agency will continue to closely monitor the safety of Halaven. To date, no safety reports have been received that could be attributed to misinterpretation of the dosing instructions.

What are the recommendations for healthcare professionals?

- Doctors are reminded that the recommended dose in the EU is 1.23 mg/m^2, which is expressed in terms of active substance (eribulin).
- Doctors are also reminded that in some countries, like the USA, and in the main clinical study with Halaven (EMBRACE), the dose is expressed as the salt, 'eribulin mesilate'.
- As for all medicines, healthcare professionals should report any adverse events suspected to be associated with Halaven.

The current European public assessment report for Halaven can be found on the Agency's website: www.ema.europa.eu/Find medicine/Human medicines/European public assessment reports.