LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Eribulin Glenmark
(eribulin mesilate, eribulin)

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Solution for injection, 0,44 mg/ml

This is a summary of the public assessment report (PAR) for Eribulin Glenmark. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Eribulin Glenmark and what is it used for?

The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Halaven .

It is used in adults for locally advanced or metastatic breast cancer (breast cancer that has spread beyond the original tumour) when at least one other therapy has been tried but has lost its effect.

It is also used in adults for advanced or metastatic liposarcoma (a type of cancer that arises from fat tissue) when previous therapy has been tried but has lost its effect.

How does Eribulin Glenmark work?

Eribulin Glenmark contains the active substance eribulin and is an anti-cancer medicine which works by stopping the growth and spread of cancer cells.

How is Eribulin Glenmark used?

The pharmaceutical form is solution for injection.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Eribulin Glenmark have been shown in studies?

No additional studies were needed as the product is a generic medicine that is given by intravenous injection and contains the same active substance as the reference medicine, Halaven.

What are the possible side effects from Eribulin Glenmark?

Because the product is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Eribulin Glenmark approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be therapeutically equivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Halaven, the benefits are greater than its risks and recommended that it can be approved for use.

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

A risk management plan has been developed to ensure that the product 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, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Eribulin Glenmark

The full PAR for Eribulin Glenmark can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Eribulin Glenmark, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in YYYY-MM.