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Gefitinib Mylan (*gefitinib*)

An overview of Gefitinib Mylan and why it is authorised in the EU

What is Gefitinib Mylan and what is it used for?

Gefitinib Mylan is used to treat adults who have non-small cell lung cancer that is locally advanced or metastatic (when cancer cells have spread from the original site to other parts of the body). It is used in patients whose cancer cells have a mutation in the genes that make a protein called epidermal growth factor receptor (EGFR).

Gefitinib Mylan contains the active substance gefitinib and is a 'generic medicine'. This means that Gefitinib Mylan contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU called Iressa. For more information on generic medicines, see the question-and-answer document here.

How is Gefitinib Mylan used?

Gefitinib Mylan can only be obtained with a prescription and treatment should be started and supervised by a doctor who has experience with anticancer treatments.

Gefitinib Mylan is available as 250 mg tablets to be taken by mouth. The recommended dose is one tablet once a day. The tablet can be dispersed in water for patients who have difficulty swallowing.

For more information about using Gefitinib Mylan, see the package leaflet or contact your doctor or pharmacist.

How does Gefitinib Mylan work?

The active substance in Gefitinib Mylan, gefitinib, is a protein tyrosine kinase inhibitor. This means that it blocks specific enzymes known as tyrosine kinases. These enzymes can be found on the surface of cancer cells, such as EGFR on the surface of non-small cell lung cancer cells. EGFR is involved in the growth and spread of cancer cells. By blocking EGFR, Gefitinib Mylan helps to slow down the growth and spread of the cancer. Gefitinib Mylan works only in non-small cell lung cancer cells that have a mutation in their EGFR.

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How has Gefitinib Mylan been studied?

Studies on the benefits and risks of the active substance in the authorised use have already been carried out with the reference medicine, Iressa, and do not need to be repeated for Gefitinib Mylan.

As for every medicine, the company provided studies on the quality of Gefitinib Mylan. The company also carried out a study that showed that it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

What are the benefits and risks of Gefitinib Mylan?

Because Gefitinib Mylan 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 Gefitinib Mylan authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Gefitinib Mylan has been shown to have comparable quality and to be bioequivalent to Iressa. Therefore, the Agency's view was that, as for Iressa, the benefit of Gefitinib Mylan outweighs the identified risk and it can be authorised for use in the EU.

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

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

As for all medicines, data on the use of Gefitinib Mylan are continuously monitored. Side effects reported with Gefitinib Mylan are carefully evaluated and any necessary action taken to protect patients.

Other information about Gefitinib Mylan

Gefitinib Mylan received a marketing authorisation valid throughout the EU on 27 September 2018.

Further information on Gefitinib Mylan can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. Information on the reference medicine can also be found on the Agency's website.

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