EMA/336347/2014
EMEA/H/C/002594

EPAR summary for the public

Imatinib Actavis

imatinib

This is a summary of the European public assessment report (EPAR) for Imatinib Actavis. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Imatinib Actavis.

For practical information about using Imatinib Actavis, patients should read the package leaflet or contact their doctor or pharmacist.

What is Imatinib Actavis and what is it used for?

Imatinib Actavis is an anticancer medicine that contains the active substance imatinib. It is used to treat the following diseases:

- chronic myeloid leukaemia (CML), a cancer of the white blood cells in which granulocytes (a type of white blood cell) start growing out of control. Imatinib Actavis is used when the patients are 'Philadelphia-chromosome positive' (Ph+). This means that some of their genes have re-arranged themselves to form a special chromosome called the Philadelphia chromosome. It is used in children who have been newly diagnosed with Ph+ CML and who are not eligible for a bone marrow transplant. It is also used in children in the 'chronic phase' of the disease if it is not responding to interferon alpha (another medicine used to treat cancer), and in more advanced phases of the disease ('accelerated phase' and 'blast crisis'). Imatinib Actavis is also used in adults with Ph+ CML in blast crisis.
- Ph+ acute lymphoblastic leukaemia (ALL), a type of cancer in which lymphocytes (another type of white blood cell) multiply too quickly. Imatinib Actavis is used in combination with other anticancer medicines in adults who have been newly diagnosed with Ph+ ALL. It is also used alone to treat adults with Ph+ ALL that has returned following previous treatment, or is not responding to other medicines.
- myelodysplastic or myeloproliferative diseases (MD/MPD), a group of diseases in which the body produces large numbers of abnormal blood cells. Imatinib Actavis is used to treat adults with

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

MD/MPD who have re-arrangements of the gene for platelet-derived growth factor receptor (PDGFR);

- advanced hypereosinophilic syndrome (HES) or chronic eosinophilic leukaemia (CEL), diseases in which eosinophils (another type of white blood cell) start growing out of control. Imatinib Actavis is used to treat adults with HES or CEL who have a specific re-arrangement of two genes called FIP1L1 and PDGFRα;
- dermatofibrosarcoma protuberans (DFSP), a type of cancer (sarcoma) in which cells in the tissue beneath the skin divide uncontrollably. Imatinib Actavis is used to treat adults with DFSP that cannot be removed with surgery, and in adults who are not eligible for surgery when the cancer has returned after treatment or has spread to other parts of the body.

Imatinib Actavis is a 'generic medicine'. This means that Imatinib Actavis is similar to a 'reference medicine' already authorised in the European Union (EU) called Glivec. For more information on generic medicines, see the question-and-answer document here.

How is Imatinib Actavis used?

Imatinib Actavis is available as capsules (50, 100 and 400 mg) and tablets (100 and 400 mg). The medicine can only be obtained with a prescription and treatment should be started by a doctor who has experience in the treatment of patients with cancers of the blood. Imatinib Actavis is given by mouth with a meal and a large glass of water to reduce the risk of irritation of the stomach and gut. The dose depends on the age and condition of the patient, and the response to treatment, but it should not exceed 800 mg a day. For more information, see the package leaflet.

How does Imatinib Actavis work?

The active substance in Imatinib Actavis, imatinib, is a protein-tyrosine-kinase inhibitor. This means that it blocks some specific enzymes known as tyrosine kinases. These enzymes can be found in some receptors on the surface of cancer cells, including the receptors that are involved in stimulating the cells to divide uncontrollably. By blocking these receptors, Imatinib Actavis helps to control cell division.

How has Imatinib Actavis been studied?

Because Imatinib Actavis is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Glivec. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefits and risks of Imatinib Actavis?

Because Imatinib Actavis 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 Imatinib Actavis approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Imatinib Actavis has been shown to have comparable quality and to be bioequivalent to Glivec. Therefore, the CHMP's view was that, as for Glivec, the benefit outweighs the identified risk. The Committee recommended that Imatinib Actavis be approved for use in the EU.

What measures are being taken to ensure the safe and effective use of Imatinib Actavis?

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

Other information about Imatinib Actavis

The European Commission granted a marketing authorisation valid throughout the European Union for Imatinib Actavis on 17 April 2013.

The full EPAR for Imatinib Actavis can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Imatinib Actavis, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 04-2014.