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EPAR summary for the public

Imatinib medac

imatinib

This is a summary of the European public assessment report (EPAR) for Imatinib medac. 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 medac.

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

What is Imatinib medac and what is it used for?

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

- Children with 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 medac 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. Imatinib medac 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 anticancer medicine), and in more advanced phases of the disease ('accelerated phase' and 'blast crisis').
- Adults with Ph+ CML in blast crisis;
- Adults and children with Ph+ acute lymphoblastic leukaemia (ALL), a type of cancer in which lymphocytes (another type of white blood cell) multiply too quickly. Imatinib medac is used in combination with other anticancer medicines in patients who have been newly diagnosed with Ph+ ALL. It is also used alone in adults to treat Ph+ ALL that has returned following previous treatment, or is not responding to other medicines;
- Adults with myelodysplastic or myeloproliferative diseases (MDS/MPD), a group of diseases in which the body produces large numbers of abnormal blood cells. Imatinib medac is used to treat

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

- Adults with 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 medac is used to treat adults with HES or CEL who have a specific re-arrangement of two genes called FIP1L1 and PDGFRα;
- Adults with dermatofibrosarcoma protuberans (DFSP), a type of cancer (sarcoma) in which cells in the tissue beneath the skin divide uncontrollably. Imatinib medac 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 medac is a 'generic medicine'. This means that Imatinib medac 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 medac used?

Imatinib medac is available as capsules (100 and 400 mg). It 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 or solid tumours. Imatinib medac 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 disease being treated, 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 medac work?

The active substance in Imatinib medac, 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 certain receptors in cancer cells, including the receptors that are involved in stimulating the cells to divide uncontrollably. By blocking these receptors, Imatinib medac helps to control cell division.

How has Imatinib medac been studied?

Because Imatinib medac 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 medac?

Because Imatinib medac 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 medac approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Imatinib medac 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 medac be approved for use in the EU.

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

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

Other information about Imatinib medac

The European Commission granted a marketing authorisation valid throughout the European Union for Imatinib medac on 25 September 2013.

The full EPAR for Imatinib medac 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 medac, 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 04-2015.