



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EPAR summary for the public

Imatinib Teva

imatinib

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

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

What is Imatinib Teva and what is it used for?

Imatinib Teva is a cancer medicine. 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 Teva 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 Teva is used in adults and children who have been newly diagnosed with Ph+ CML and who are not eligible for a bone marrow transplant. It is also used in adults and children in the 'chronic phase' of the disease if it is not responding to interferon alpha (another cancer medicine), and in more advanced phases of the disease ('accelerated phase' and 'blast crisis');
- Ph+ acute lymphoblastic leukaemia (ALL), a type of cancer in which lymphocytes (another type of white blood cell) multiply too quickly. Imatinib Teva is used in combination with other cancer medicines in adults and children 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;
- myelodysplastic or myeloproliferative diseases (MD/MPD), a group of diseases in which the body produces large numbers of abnormal blood cells. Imatinib Teva is used to treat adults with 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 Teva is used to treat adults with HES or CEL who have a specific re-arrangement of two genes called FIP1L1 and PDGFR α ;
- dermatofibrosarcoma protuberans (DFSP), a type of cancer (sarcoma) in which cells in the tissue beneath the skin divide uncontrollably. Imatinib Teva 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 Teva contains the active substance imatinib. It is a 'generic medicine'. This means that Imatinib Teva 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 Teva used?

Imatinib Teva 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. It is available as capsules (100 and 400 mg) and tablets (100 and 400 mg) and 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 Teva work?

The active substance in Imatinib Teva, 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 Teva helps to control cell division.

How has Imatinib Teva been studied?

Because Imatinib Teva is a generic medicine, studies in patients have been limited to tests to determine that the tablets and capsules are 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 Teva?

Because Imatinib Teva 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 Teva approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Imatinib Teva 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 Teva be given marketing authorisation.

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

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

Other information about Imatinib Teva

The European Commission granted a marketing authorisation valid throughout the European Union for Imatinib Teva on 8 January 2013.

The full EPAR for Imatinib Teva 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 Teva, 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 09-2016.