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EPAR summary for the public

Imatinib Teva B.V.

imatinib

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

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

What is Imatinib Teva B.V. and what is it used for?

Imatinib Teva B.V. is a cancer medicine that 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 Teva B.V. 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 B.V. 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 alfa (a medicine used for treating some cancers), 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 Teva B.V. is used in combination with other cancer 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;

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- adults with myelodysplastic or myeloproliferative diseases (MD/MPD), a group of diseases in which the body produces large numbers of abnormal blood cells. Imatinib Teva B.V. is used to treat adults with MD/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 Teva B.V. is used to treat adults with HES or CEL who have a specific re-arrangement of two genes called FIP1L1 and PDGFRα;
- adults with gastrointestinal stromal tumours (GIST), a type of cancer (sarcoma) of the stomach and bowel, when there is uncontrolled growth of cells in the supporting tissues of these organs. Imatinib Teva B.V. is used to treat adults with GIST that cannot be removed by surgery or have spread to other parts of the body, and adults who are at risk of GIST coming back after surgical removal;
- adults with dermatofibrosarcoma protuberans (DFSP), a type of cancer (sarcoma) in which cells in the tissue beneath the skin divide uncontrollably. Imatinib Teva B.V. is used to treat adults with DFSP that cannot be removed by 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 B.V. contains the active substance imatinib and is a 'generic medicine'. This means that Imatinib Teva B.V. 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 B.V. used?

Imatinib Teva B.V. is available as capsules (100 and 400 mg) and tablets (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 with solid tumours.

Imatinib Teva B.V. 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 B.V. work?

The active substance in Imatinib Teva B.V., 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 involved in stimulating the cells to divide uncontrollably. By blocking these enzymes, Imatinib Teva B.V. helps to control cell division.

How has Imatinib Teva B.V. been studied?

Studies on the benefits and risks of the active substance in the approved uses have already been carried out with the reference medicine, Glivec, and do not need to be repeated for Imatinib Teva B.V.

As for every medicine, the company provided studies on the quality of Imatinib Teva B.V. The company also carried out studies 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 Imatinib Teva B.V.?

Because Imatinib Teva B.V. 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 B.V. approved?

The European Medicines Agency concluded that, in accordance with EU requirements, Imatinib Teva B.V. has been shown to have comparable quality and to be bioequivalent to Glivec. Therefore, the Agency's view was that, as for Glivec, the benefit outweighs the identified risk. The Agency recommended that Imatinib Teva B.V. be approved for use in the EU.

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

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

Other information about Imatinib Teva B.V.

The European Commission granted a marketing authorisation valid throughout the European Union for Imatinib Teva B.V. on 15 November 2017.

The full EPAR for Imatinib Teva B.V. 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 B.V., 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 03-2017.