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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 Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Imatinib Teva.

What is Imatinib Teva?

Imatinib Teva is a medicine that contains the active substance imatinib. It is available as capsules (100 and 400 mg) and tablets (100 and 400 mg).

Imatinib Teva 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.

What is Imatinib Teva used for?

Imatinib Teva is an anticancer medicine. 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 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 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;

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- adults with Ph+ acute lymphoblastic leukaemia (ALL), a type of cancer in which lymphocytes (another type of white blood cell) multiply too quickly. It 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 Ph+ ALL that has returned following previous treatment, or is not responding to other medicines;
- adults with myelodysplastic or myeloproliferative diseases (MD/MPD), a group of diseases in which the body produces large numbers of abnormal blood cells. It 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. It 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. It 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.

The medicine can only be obtained with a prescription.

How is Imatinib Teva used?

Imatinib Teva treatment should be started by a doctor who has experience in the treatment of patients with cancers of the blood. Imatinib Teva 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 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 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 has Imatinib Teva been approved?

The 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.

Other information about Imatinib Teva

The European Commission granted a marketing authorisation valid throughout the European Union for Imatinib Teva on 08 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 06-2013.