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EPAR summary for the public

Glivec

imatinib

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

What is Glivec?

Glivec is a medicine that contains the active substance imatinib. It is available as capsules (50 and 100 mg) and tablets (100 and 400 mg).

What is Glivec used for?

Glivec is an anticancer 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. Glivec 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. Glivec 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 anticancer 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. Glivec is used in combination with other anticancer medicines in adults and children 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.

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- myelodysplastic or myeloproliferative diseases (MD/MPD), a group of diseases in which the body produces large numbers of abnormal blood cells. Glivec 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. Glivec is used to treat adults with HES or CEL who have a specific re-arrangement of two genes called FIP1L1 and PDGFRα;
- 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. Glivec is used to treat adults with GIST that cannot be removed with surgery or have spread to other parts of the body, and adults who are at risk of GIST coming back after surgical removal;
- dermatofibrosarcoma protuberans (DFSP), a type of cancer (sarcoma) in which cells in the tissue beneath the skin divide uncontrollably. Glivec 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 Glivec used?

Glivec treatment should be started by a doctor who has experience in the treatment of patients with cancers of the blood or solid tumours. Glivec 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 Glivec work?

The active substance in Glivec, 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, Glivec helps to control cell division.

How has Glivec been studied?

For CML, Glivec has been examined in four main studies involving 2,133 adults and one study of 54 children. These included a study involving 1,106 adults that compared Glivec with the combination of interferon alpha plus cytarabine (other anticancer medicines). This study measured how long the patients lived without their cancer getting worse.

For Ph+ ALL, Glivec has been examined in three studies involving 456 adults, including one study comparing Glivec with standard chemotherapy (medicines used to kill cancer cells) in 55 newly diagnosed patients. It has also been examined in a fourth main study involving 160 children and young people aged 1 to 22 years.

For GIST, Glivec has been examined in two main studies. One involved 147 patients whose GIST could not be surgically removed or had spread to other parts of the body, and looked at whether the tumours shrank in size. This study did not compare Glivec with any other medicines. The other study compared Glivec with placebo (a dummy treatment) in 713 patients whose cancer had been removed with surgery. This study measured how long the patients lived without their cancer coming back.

For MD/MPD (31 patients), HES and CEL (176 patients), and DFSP (18 patients), Glivec was not compared with any other medicines. These studies examined whether blood cell counts returned to normal levels, or whether the number of cancerous blood cells or the size of tumours fell.

What benefit has Glivec shown during the studies?

Glivec was more effective than the comparator medicines. In patients with CML, the cancer had got worse in 16% of the patients taking Glivec after five years, compared with 28% of those taking interferon alpha plus cytarabine. Glivec was also better than standard chemotherapy in patients with Ph+ ALL. In patients with GIST that had been removed with surgery, patients taking Glivec lived for longer than those taking placebo without their cancer coming back. In the non-comparative studies of CML, Ph+ ALL and GIST, between 26 and 96% of patients showed a response to Glivec. In the study of patients aged 1 to 22 years who had Ph+ ALL, Glivec was shown to increase how long the patients lived without any major events (such as a relapse).

Due to their rarity, limited data were available for the other diseases, but around two thirds of the patients showed at least a partial response to Glivec.

What is the risk associated with Glivec?

The most common side effects with Glivec (seen in more than 1 in 10 patients) are weight increase, neutropenia (low levels of the white blood cells that fight infection), thrombocytopenia (low blood platelet counts), anaemia (low red blood cell counts), headache, nausea (feeling sick), vomiting, diarrhoea, dyspepsia (indigestion), abdominal (tummy) pain, periorbital oedema (swelling around the eyes), rash, muscle spasm and cramps, muscle, bone and joint pain, fluid retention and fatigue (tiredness). For the full list of all side effects reported with Glivec, see the package leaflet.

Glivec must not be used in people who are hypersensitive (allergic) to imatinib or any of the other ingredients.

Why has Glivec been approved?

The CHMP decided that Glivec's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Glivec

The European Commission granted a marketing authorisation valid throughout the European Union for Glivec on 7 November 2001.

The full EPAR for Glivec 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 Glivec, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 06-2013.