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Imatinib Koanaa (*imatinib*)

An overview of Imatinib Koanaa and why it is authorised in the EU

What is Imatinib Koanaa and what is it used for?

Imatinib Koanaa is a cancer medicine for treating adults and 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 Koanaa 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 Koanaa 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 Koanaa 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.

This medicine is also used for treating adults with:

- myelodysplastic or myeloproliferative diseases (MD/MPD), a group of diseases in which the body produces large numbers of abnormal blood cells. Imatinib Koanaa 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 Koanaa 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 that arises from uncontrolled cell growth of the supporting tissues of the stomach and bowels. Imatinib Koanaa is used when patients are 'Kit (CD117) positive'. This means that the cancer cells have a specific protein called Kit (CD117) on their surface. Imatinib Koanaa is used when GIST cannot be removed

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with surgery, and/or when the cancer has spread to other parts of the body. It is also used to treat adult patients in which the cancer is likely to come back after surgical removal of GIST;

- dermatofibrosarcoma protuberans (DFSP), a type of cancer (sarcoma) in which cells in the tissue beneath the skin divide uncontrollably. Imatinib Koanaa 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 Koanaa is a type of 'generic medicine' called a 'hybrid medicine'. This means that it is similar to a 'reference medicine' containing the same active substance, but the medicine is presented in a different way. While the reference medicine, Glivec, is available as film-coated tablets, Imatinib Koanaa is available as an oral solution (a liquid to be drunk). For more information on generic and hybrid medicines, see the question-and-answer document here.

Imatinib Koanaa contains the active substance imatinib.

How is Imatinib Koanaa used?

Imatinib Koanaa 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. It is available as oral solution (80 mg/ml) and is given 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 about using Imatinib Koanaa, see the package leaflet or contact your healthcare provider.

How does Imatinib Koanaa work?

The active substance in Imatinib Koanaa, 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 (targets for hormones or other active substances) in cancer cells, including the receptors that are involved in stimulating the cells to divide uncontrollably. By blocking these receptors, Imatinib Koanaa helps to control cell division.

How has Imatinib Koanaa been studied?

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

As for every medicine, the company provided studies on the quality of Imatinib Koanaa. The company also carried out a study 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 Koanaa?

Because Imatinib Koanaa is a hybrid 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 Koanaa authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Imatinib Koanaa has been shown to have comparable quality and to be bioequivalent to reference medicine. Therefore, the Agency's view was that, as for Glivec, the benefits of Imatinib Koanaa outweigh the identified risks and it can be authorised for use in the EU.

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

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

As for all medicines, data on the use of Imatinib Koanaa are continuously monitored. Suspected side effects reported with Imatinib Koanaa are carefully evaluated and any necessary action taken to protect patients.

Other information about Imatinib Koanaa

Imatinib Koanaa received a marketing authorisation valid throughout the EU on 22 September 2021.

Further information on Imatinib Koanaa can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/Imatinib-Koanaa

Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 09-2021.