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Nilotinib Accord (*nilotinib*)

An overview of Nilotinib Accord and why it is authorised in the EU

What is Nilotinib Accord and what is it used for?

Nilotinib Accord is a medicine for treating chronic myelogenous leukaemia (CML) – a blood cancer – in patients who have been newly diagnosed or who cannot take other cancer medicines (including imatinib) because they cause side effects or do not work for them.

Nilotinib Accord is only for patients with a special chromosome in their cancer cells called the Philadelphia chromosome. Nilotinib Accord is used during the chronic phase of the cancer in adults and children, when the condition is developing slowly and the patient has few or no symptoms. It can also be used in adults during the accelerated phase (when the cancer cells are dividing rapidly and the patient may have more symptoms).

Nilotinib Accord contains the active substance nilotinib and is a 'generic medicine'. This means that Nilotinib Accord contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU. The reference medicine for Nilotinib Accord is Tasigna. For more information on generic medicines, see the question-and-answer document here.

How is Nilotinib Accord used?

Nilotinib Accord can only be obtained with a prescription and treatment should be started by a doctor who has experience in the diagnosis and treatment of CML.

The medicine is available as capsules to be taken twice a day on an empty stomach. Treatment can continue for as long as the patient benefits from it. Adults whose CML is well controlled may stop treatment but should have regular tests to check that the disease has not started to come back.

For more information about using Nilotinib Accord, see the package leaflet or contact your doctor or pharmacist.

How does Nilotinib Accord work?

The active substance in Nilotinib Accord, nilotinib, belongs to a group of medicines called 'protein kinase inhibitors'. Nilotinib acts by blocking the protein kinase called BCR-ABL kinase which is produced by leukaemia cells that have the Philadelphia chromosome and causes them to multiply uncontrollably. By blocking BCR-ABL kinase, Nilotinib helps to control the spread of leukaemia cells.

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How has Nilotinib Accord been studied?

Studies on the benefits and risks of the active substance in the authorised use have already been carried out with the reference medicine, Tasigna, and do not need to be repeated for Nilotinib Accord.

As for every medicine, the company provided studies on the quality of Nilotinib Accord. 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 Nilotinib Accord?

Because Nilotinib Accord 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 Nilotinib Accord authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Nilotinib Accord has been shown to have comparable quality and to be bioequivalent to Tasigna. Therefore, the Agency's view was that, as for Tasigna, the benefits of Nilotinib Accord 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 Nilotinib Accord?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Nilotinib Accord have been included in the summary of product characteristics and the package leaflet. Any additional measures in place for Tasigna also apply to Nilotinib Accord where appropriate.

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

Other information about Nilotinib Accord

Nilotinib Accord received a marketing authorisation valid throughout the EU on 22 August 2024.

Further information on Nilotinib Accord can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/nilotinib-accord. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 08-2024.