EMA/124586/2022
EMEA/H/C/005446

Dasatinib Accord (*dasatinib*)

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

What is Dasatinib Accord and what is it used for?

Dasatinib Accord is a cancer medicine. It is used to treat 'Philadelphia chromosome positive' (Ph+) acute lymphoblastic leukaemia (ALL) in adults when other treatments do not work or cause troublesome side effects. It is also used in children with newly diagnosed Ph+ ALL in combination with chemotherapy (cancer medicines).

Ph+ ALL is a cancer of lymphocytes (a type of white blood cells). In this disease, the lymphocytes multiply too quickly and live for too long. Ph+ means that some of the patient's genes have rearranged themselves to form a special chromosome called the Philadelphia chromosome which produces an enzyme, Bcr-Abl kinase, that leads to the development of leukaemia.

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

How is Dasatinib Accord used?

Dasatinib 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 leukaemia.

The medicine is available as tablets to be taken by mouth, consistently either in the morning or in the evening. The dose in adults is 140 mg once a day. In children, the dose depends on their body weight and can be gradually increased until the disease is controlled well enough. In children who are also receiving other cancer medicines, a fixed dose of Dasatinib Accord is used throughout their treatment. In children weighing less than 10 kg, other dasatinib products should be used that allow a lower dose to be given.

The doctor may reduce the dose or interrupt treatment if blood cell counts are too low, if certain side effects occur or if the medicine no longer controls the condition.

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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

How does Dasatinib Accord work?

The active substance in Dasatinib Accord, dasatinib, belongs to a group of medicines that block enzymes known as protein kinases. Dasatinib acts mainly by blocking the Bcr-Abl protein kinase. This enzyme is produced by leukaemia cells, and causes them to multiply uncontrollably. By blocking Bcr-Abl kinase, as well as other kinases, Dasatinib Accord helps to reduce the number of leukaemia cells.

How has Dasatinib Accord 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, Sprycel, and do not need to be repeated for Dasatinib Accord.

As for every medicine, the company provided data on the quality of Dasatinib 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 Dasatinib Accord?

Because Dasatinib 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 Dasatinib Accord authorised in the EU?

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

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

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

Other information about Dasatinib Accord

Dasatinib Accord received a marketing authorisation valid throughout the EU on 24 March 2022.

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

This overview was last updated in 03-2022.