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Dasatinib Accord Healthcare (*dasatinib*)

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

What is Dasatinib Accord Healthcare and what is it used for?

Dasatinib Accord Healthcare is a cancer medicine. It is used to treat adults with the following types of leukaemia (cancer of the white blood cells):

- chronic myeloid leukaemia (CML) in the 'chronic' phase in newly diagnosed patients who are 'Philadelphia chromosome positive' (Ph+). In CML, granulocytes (a type of white blood cell) start growing out of control. 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.
- CML in 'chronic', 'accelerated' and 'blast' phases. Dasatinib Accord Healthcare is used when other treatments including imatinib (another cancer medicine) do not work or cause troublesome side effects;
- Ph+ acute lymphoblastic leukaemia (ALL), where lymphocytes (another type of white blood cell) multiply too quickly, or in 'lymphoid blast' CML. Dasatinib Accord Healthcare is used when other treatments do not work or cause troublesome side effects.

Dasatinib Accord Healthcare is also used in children to treat:

- newly diagnosed Ph+ CML in the 'chronic' phase, or Ph+ CML when other treatments including imatinib cannot be given or have not worked;
- newly diagnosed Ph+ ALL in combination with chemotherapy (cancer medicines).

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

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How is Dasatinib Accord Healthcare used?

Dasatinib Accord Healthcare 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.

Dasatinib Accord Healthcare is available as tablets to be taken by mouth. It is taken once a day, consistently either in the morning or in the evening.

The starting dose depends on the condition being treated and, for children, their body weight. The dose is then gradually increased until the disease is controlled well enough. In children with ALL who are also receiving other cancer medicines, a fixed dose of Dasatinib Accord Healthcare is used throughout their treatment. The doctor may reduce the dose or interrupt treatment if blood cell counts are too low or certain side effects occur. Treatment is stopped if the medicine no longer controls the condition or if the patient cannot take the medicine because of side effects.

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

How does Dasatinib Accord Healthcare work?

The active substance in Dasatinib Accord Healthcare, 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 Healthcare helps to reduce the number of leukaemia cells.

How has Dasatinib Accord Healthcare 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 Healthcare.

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

Because Dasatinib Accord Healthcare 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 Healthcare authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Dasatinib Accord Healthcare 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 Healthcare 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 Healthcare?

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

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

Other information about Dasatinib Accord Healthcare

Dasatinib Accord Healthcare received a marketing authorisation valid throughout the EU on 26 July 2024.

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

This overview was last updated in 07-2024.