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Dasatinib Accordpharma (*dasatinib*)

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

Medicinal product no longer authorised

What is Dasatinib Accordpharma and what is it used for?

Dasatinib Accordpharma 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 Accordpharma 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 and live for too long, or in 'lymphoid blast' CML. Dasatinib Accordpharma is used when other treatments do not work or cause troublesome side effects.

Dasatinib Accordpharma 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 Accordpharma contains the active substance dasatinib and is a 'generic medicine'. This means that Dasatinib Accordpharma 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 Accordpharma used?

Dasatinib Accordpharma 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.

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The medicine is available as tablets. 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 Accordpharma 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 Accordpharma, see the package leaflet or contact your doctor or pharmacist.

How does Dasatinib Accordpharma work?

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

How has Dasatinib Accordpharma 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 Accordpharma.

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

Because Dasatinib Accordpharma 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 Accordpharma authorised in the EU?

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

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

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

Other information about Dasatinib Accordpharma

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

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

This overview was last updated in 03-2022.

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