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Bosulif (*bosutinib*)

An overview of Bosulif and why it is authorised in the EU

What is Bosulif and what is it used for?

Bosulif is a cancer medicine that is used to treat chronic myeloid leukaemia (CML), a cancer of the white blood cells, in adults with a special chromosome in their cells called the Philadelphia chromosome.

It is used to treat three stages of CML called 'chronic phase', 'accelerated phase' and 'blast phase' in patients who have already been treated with one or more tyrosine kinase inhibitors (medicines for CML which work in a similar way to Bosulif), and when the tyrosine kinase inhibitors called dasatinib, imatinib and nilotinib are not suitable.

Bosulif is also used to treat newly diagnosed patients who are in the 'chronic phase' of CML.

Bosulif contains the active substance bosutinib.

How is Bosulif used?

Bosulif is available as tablets . It can only be obtained with a prescription and treatment should be started by a doctor who is experienced in the diagnosis and treatment of CML. The recommended dose is 400 mg once a day for newly diagnosed patients, and 500 mg once a day for patients who have already been treated with other medicines. The doctor may increase the dose up to 600 mg once a day or reduce it or interrupt treatment according to how the medicine is working and the side effects the patient has.

For more information about using Bosulif, see the package leaflet or contact a doctor or pharmacist.

How does Bosulif work?

The active substance in Bosulif, bosutinib, is a tyrosine kinase inhibitor (TKI). It blocks the action of enzymes known as Src and Bcr-Abl tyrosine kinases found on leukaemia cells where they are involved in stimulating the cells to divide uncontrollably. By blocking their action, Bosulif helps to control cell division, thereby controlling the growth and spread of the leukaemia cells in CML.

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What benefits of Bosulif have been shown in studies?

Studies have shown that Bosulif is effective at reducing the proportion of white blood cells with the Philadelphia chromosome. Bosulif was investigated in one main study involving 570 patients with 'Philadelphia chromosome positive' (Ph+) CML who had previously been treated with at least one tyrosine kinase inhibitor. Bosulif was not compared with another treatment. Of these, 52 patients were considered to have an unmet medical need, because disease resistance or the risk of severe side effects made other tyrosine kinase inhibitors unsuitable. Among these patients, 36 had chronic phase CML and 16 had either accelerated or blast phase CML.

The main measure of effectiveness was the number of patients who had at least a 'major cytogenetic response' (where the proportion of white blood cells with the Philadelphia chromosome fell below 35%) after six months of Bosulif treatment. Effectiveness was also measured in other ways including 'haematological response' (a return to normal of the number of white cells in the blood). Bosulif treatment was effective in patients with an unmet medical need: 18 out of 36 patients with chronic phase CML had a 'major cytogenetic response', while 7 out of the 16 patients with advanced (accelerated or blast phase) CML also had a sufficient response based on other measurements.

Results from an extension of this study, during which patients who benefited from Bosulif were followed up for at least 10 years, confirmed that the effect of the medicine was maintained long-term.

An additional study involved 163 patients with chronic or advanced Ph+ CML for whom previous treatment with at least one tyrosine kinase inhibitor did not work, or who could not take these medicines. The study showed that among the 156 patients with chronic Ph+ CML treated with at least one TKI, 72% had a major cytogenetic response. Among the 7 patients with advanced CML, 75% had an haematological response after one year of treatment.

A third study in 536 newly diagnosed CML patients in the 'chronic phase' compared Bosulif with imatinib. The main measure of effectiveness was the number of patients who had a 'major molecular response' (where the amount in the bone marrow of BCR-ABL, the protein produced by the Philadelphia chromosome, is greatly lowered). After one year of treatment, 47% (116 out of 246) of patients treated with Bosulif had a major molecular response, compared with 37% (89 out of 241) of patients treated with imatinib.

What are the risks associated with Bosulif?

The most common side effects with Bosulif (which may affect more than 1 in 5 people) are diarrhoea, nausea (feeling sick), thrombocytopenia (low blood platelet counts), abdominal pain (belly ache), vomiting, rash, anaemia (low red blood cell counts), tiredness, fever, increased levels of liver enzymes and headache. The most serious side effects (which may affect more than 1 in 20 people) include thrombocytopenia, anaemia, diarrhoea, rash, neutropenia (low levels of neutrophils, a type of white blood cell) and blood tests suggesting damage to the liver and pancreas. For the full list of side effects of Bosulif, see the package leaflet.

Bosulif must not be used in patients with reduced liver function. For the full list of restrictions, see the package leaflet.

Why is Bosulif authorised in the EU?

Bosulif has been shown to improve the condition of patients with CML, including by reducing the number of cancer cells with the Philadelphia chromosome and returning white blood cell levels to normal. The side effects of the medicine are considered to be manageable.

The European Medicines Agency therefore decided that the benefits of Bosulif are greater than its risks and it can be authorised for use in the EU.

Bosulif was originally given 'conditional authorisation' because there was more evidence to come about the medicine. As the company has supplied the additional information necessary, the authorisation has been switched from conditional to full authorisation.

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

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

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

Other information about Bosulif

Bosulif received a conditional marketing authorisation valid throughout the EU on 27 March 2013. This was switched to a full marketing authorisation on 7 April 2022.

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

This overview was last updated in 05-2022.