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Tasigna (*nilotinib*)

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

What is Tasigna and what is it used for?

Tasigna 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.

Tasigna is only for patients with a special chromosome in their cancer cells called the Philadelphia chromosome. Tasigna 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).

CML is rare, and Tasigna was designated an 'orphan medicine' (a medicine used in rare diseases) on 22 May 2006. Further information on the orphan designation can be found here: ema.europa.eu/Find medicine/Human medicines/Rare disease designation.

Tasigna contains the active substance nilotinib.

How is Tasigna used?

The medicine is available as capsules to be taken twice a day on an empty stomach. For patients who are unable to swallow capsules the content of the capsules can be mixed in a teaspoon of apple puree and swallowed.

The dose of Tasigna depends on the age of the patient and whether they have previously had treatment for CML, as well as the phase of the disease. 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 Tasigna, see the package leaflet or contact your doctor or pharmacist.

Tasigna 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.

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How does Tasigna work?

The active substance in Tasigna, 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, Tasigna helps to control the spread of leukaemia cells.

What benefits of Tasigna have been shown in studies?

A number of studies have shown that Tasigna has important effects which can help keep CML under control. Below is a brief description of the studies and what effects they measured:

- A study in 320 adults with chronic phase CML showed that treatment with Tasigna can lead to what is known as a major cytogenetic response (when the proportion of white blood cells in the bone marrow containing the Philadelphia chromosome falls to below 35%). In this study around 49% of patients, most of whom had stopped responding to imatinib, achieved this response after around 11 months on Tasigna treatment.
- Another study in 119 adults with accelerated phase CML looked at the haematological response (when the number of white cells in the blood returns to normal). This response was achieved in 42% of patients, most of whom had also stopped responding to imatinib, after around seven months of Tasigna treatment.
- A third study in 846 newly diagnosed adults with chronic phase CML compared Tasigna with imatinib. It focused on another measure called a major molecular response (when the proportion of the patient's white blood cells that can produce the abnormal Bcr-Abl kinase falls to below 0.1%). Depending on the dose, between 43% and 44% of patients taking Tasigna achieved this response after 12 months compared with 22% of patients taking imatinib.
- Two further studies in adults with chronic phase CML who were treated with Tasigna for at least 3 years and whose disease was well controlled for at least a year showed that the medicine's benefits can be maintained after stopping treatment. In one of the studies in 190 patients initially treated with Tasigna, 52% maintained a response after 48 weeks of stopping Tasigna. In the second study in 126 patients who had been switched from imatinib to Tasigna, 58% maintained their response 48 weeks after stopping Tasigna.
- Finally, a study showed that Tasigna was also effective in children with CML in the chronic phase. In this study of 58 children, a major molecular response was achieved with Tasigna at 6 months in 39% of children whose cancer did not respond to other medicines such as imatinib, and 64% of those with newly diagnosed cancer by 12 months.

What are the risks associated with Tasigna?

The most common side effects with Tasigna (which may affect more than 1 in 10 people) are thrombocytopenia (low blood platelet counts), neutropenia (low white blood cell counts), headache, nausea (feeling sick), rash, pruritus (itching), myalgia (muscle pain), upper abdominal (belly) pain, tiredness, hair loss and high blood levels of liver and pancreatic enzymes and bilirubin For the full list of side effects and restrictions with Tasigna, see the package leaflet.

Why is Tasigna approved?

Tasigna has been shown to improve the condition of patients with CML by reduction of the number of cancer cells with the Philadelphia chromosome and return of white blood cell levels to normal. The side

effects of the medicine are considered to be manageable. The European Medicines Agency therefore decided that Tasigna's benefits are greater than its risks and it can be authorised for use in the EU.

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

The company that markets Tasigna will provide further data on the benefits in children from an ongoing study.

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

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

Other information about Tasigna

Tasigna received a marketing authorisation valid throughout the EU on 19 November 2007.

Further information on Tasigna can be found on the Agency's website ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports.

This overview was last updated in 08-2018.