European Medicines Agency

Doc. Ref.: EMEA/398207/2009
EMEA/H/C/798

Tasigna
nilotinib

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Tasigna?
Tasigna is a medicine containing the active substance nilotinib. It is available as pale yellow capsules (200 mg).

What is Tasigna used for?
Tasigna is used to treat adults with chronic myelogenous leukaemia (CML), a type of cancer of the white blood cells where granulocytes (a type of white blood cell) start growing out of control. It is used when the patient is 'Philadelphia chromosome positive' (Ph+), which means that some of the patient's genes have re-arranged themselves to form a special chromosome called the Philadelphia chromosome. This chromosome produces an enzyme that leads to the development of leukaemia.
Tasigna is used in the 'chronic' and 'accelerated' phases of CML. There is no information available on its effectiveness in patients whose disease is in 'blast crisis' (another phase of CML).
Tasigna is used when patients cannot tolerate other treatments including imatinib (another anticancer medicine), or when their disease is not responding to them.
Because the number of patients with CML is low, the disease is considered 'rare', and Tasigna was designated an 'orphan medicine' (a medicine used in rare diseases) on 22 May 2006.
The medicine can only be obtained with a prescription.

How is Tasigna used?
Treatment with Tasigna should be initiated by a doctor who has experience in the diagnosis and treatment of CML. The recommended dose is two capsules twice a day, for as long as the patient continues to benefit. The dose should be reduced or treatment interrupted if the patient has certain side effects affecting the blood.
The two doses should be taken around 12 hours apart. The capsules are swallowed whole with a glass of water, without eating anything for two hours before and one hour after each dose. Tasigna can be given with certain other medicines if appropriate. It should be used with caution in patients who have severe problems with their liver or certain heart problems. See the Summary of Product Characteristics (also part of the EPAR) for more information.

How does Tasigna work?
The active substance in Tasigna, nilotinib, belongs to a group of medicines called protein kinase inhibitors. These compounds act by blocking types of enzymes known as protein kinases. Nilotinib

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 16
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

© European Medicines Agency,2009. Reproduction is authorised provided the source is acknowledged.

acts by blocking the protein kinase called 'Bcr-Abl' kinase. This enzyme is produced by leukaemia cells, and causes them to multiply uncontrollably. By blocking Bcr-Abl kinase, Tasigna helps to control the spread of leukaemia cells.

How has Tasigna been studied?
The effects of Tasigna were first tested in experimental models before being studied in humans.
The effectiveness of Tasigna was studied in two main studies involving a total of 439 patients with CML, who could not tolerate imatinib or whose disease had stopped responding to it. Tasigna was not compared to any other treatment.
The first study included a total of 320 patients whose disease was in the 'chronic phase', three quarters of whom had stopped responding to imatinib. Its main measure of effectiveness was the proportion of patients who had had a 'major cytogenetic response' (the proportion of the patient's white blood cells that contained the Philadelphia chromosome had fallen to below 35%). The second study included a total of 119 patients whose disease was in the 'accelerated phase', four fifths of whom had stopped responding to imatinib. Its main measure of effectiveness was the proportion of patients who had had a 'haematological response' (a return to normal of the number of white cells in the blood).

What benefit has Tasigna shown during the studies?
In the study of chronic phase CML, 156 (49%) of the 320 patients had a major cytogenetic response, after having received Tasigna for an average of 341 days (around eleven months). In the study of accelerated phase CML, 50 (42%) of the 119 patients had a haematological response, after having received Tasigna for an average of 202 days (around seven months). In both studies, Tasigna had a similar effect in patients who could not tolerate imatinib and those whose disease had stopped responding to it.

What is the risk associated with Tasigna?
The most common side effects with Tasigna (seen in more than 1 patient in 10) are thrombocytopenia (low blood platelet counts), neutropenia (low white blood cell counts), anaemia (low red blood cell counts), headache, nausea (feeling sick), constipation, diarrhoea, rash, pruritus (itching), fatigue (tiredness) and increased blood levels of lipase (an enzyme produced by the pancreas). For the full list of all side effects reported with Tasigna, see the Package Leaflet.
Tasigna should not be used in people who may be hypersensitive (allergic) to nilotinib or any of the other ingredients.

Why has Tasigna been approved?
The Committee for Medicinal Products for Human Use (CHMP) concluded that, even though it was not directly compared to any other treatment, the effectiveness of Tasigna had been demonstrated sufficiently and was the same as that of another medicine in the same class. The Committee decided that Tasigna's benefits are greater than its risks for the treatment of adults with chronic phase and accelerated phase Philadelphia chromosome positive CML with resistance or intolerance to prior therapy including imatinib. The Committee recommended that Tasigna be given marketing authorisation.

Which measures are being taken to ensure the safe use of Tasigna?
The company that makes Tasigna will provide an information pack in each Member State for doctors and pharmacists who will prescribe or dispense the medicine. The pack will remind them of how Tasigna should be used safely in patients.

Other information about Tasigna:
The European Commission granted a marketing authorisation valid throughout the European Union for Tasigna to Novartis Europharm Limited on 19 November 2007.

The summary of opinion of the Committee for Orphan Medicinal Products for Tasigna is available here.
The full EPAR for Tasigna can be found here.

This summary was last updated in 05-2009.