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EPAR summary for the public

Ninlaro

ixazomib

This is a summary of the European public assessment report (EPAR) for Ninlaro. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Ninlaro.

For practical information about using Ninlaro, patients should read the package leaflet or contact their doctor or pharmacist.

What is Ninlaro and what is it used for?

Ninlaro is a cancer medicine used to treat adults with multiple myeloma (a cancer of the bone marrow). It is given together with two other medicines, lenalidomide and dexamethasone, to patients who have received at least one prior treatment.

Because the number of patients with multiple myeloma is low, the disease is considered 'rare', and Ninlaro was designated an 'orphan medicine' (a medicine used in rare diseases) on 27 September 2011.

Ninlaro contains the active substance ixazomib.

How is Ninlaro used?

Ninlaro can only be obtained with a prescription and treatment must be started and monitored by a doctor experienced in the management of multiple myeloma.

Ninlaro is available as capsules (2.3, 3 and 4 mg) to be taken at least one hour before or two hours after food. The recommended dose is 4 mg taken once a week (on the same day of the week) for 3 consecutive weeks, followed by a week with no Ninlaro treatment. This 4-week treatment cycle should be continued until the disease gets worse or side effects become unacceptable. Treatment may need to be stopped temporarily or the dose reduced if the patient has certain side effects. The dose may be

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reduced also in patients with moderately or severely reduced liver function and patients with severely reduced kidney function.

For further information, see the package leaflet.

How does Ninlaro work?

The active substance in Ninlaro, ixazomib, is a proteasome inhibitor. This means that it blocks the proteasome, which is a system within cells that breaks down proteins when they are no longer needed. When the proteins in the cancer cells are not broken down, including the proteins that control cell growth, the cancer cells are damaged and they eventually die.

What benefits of Ninlaro have been shown in studies?

Ninlaro has been investigated in one main study involving 722 adults with multiple myeloma whose disease had not responded to or had come back after previous treatment. The study compared Ninlaro with placebo (a dummy treatment), both taken together with lenalidomide and dexamethasone. A first analysis of the data indicated that Ninlaro is effective at prolonging the time patients live without their disease getting worse (progression-free survival): patients treated with Ninlaro lived for an average of 21 months without their disease getting worse compared with 15 months in patients given placebo. However, there is uncertainty regarding the size of the improvement because further analysis of the data showed a reduced effect.

What are the risks associated with Ninlaro?

The most common side effects with Ninlaro taken together with lenalidomide and dexamethasone (seen in more than 1 in 5 people) were diarrhoea, constipation, thrombocytopenia (low blood platelet counts), peripheral neuropathy (nerve damage in the hands and feet causing tingling or numbness), nausea (feeling sick), peripheral oedema (swelling, especially of the ankles and feet), vomiting and back pain. Similar side effects were seen when lenalidomide and dexamethasone were used without Ninlaro.

For the full list of all side effects and restrictions with Ninlaro, see the package leaflet.

Why is Ninlaro approved?

Data from the main study indicate that Ninlaro improves patients' progression-free survival. However, because of the uncertainty regarding the size of the improvement following a later analysis, further confirmatory data will need to be provided by the company that markets the medicine. In addition, Ninlaro does not seem to significantly increase the frequency of serious side effects when added to lenalidomide and dexamethasone, and offers the convenience of patients being able to take the capsules at home.

The Agency's Committee for Medicinal Products for Human Use (CHMP) therefore decided that Ninlaro's benefits are greater than its risks and recommended that it be approved for use in the EU.

Ninlaro has been given 'conditional approval'. This means that there is more evidence to come about the medicine, which the company is required to provide. Every year, the European Medicines Agency will review any new information that becomes available and this summary will be updated as necessary.

What information is still awaited for Ninlaro?

Since Ninlaro has been granted a conditional approval, the company that markets Ninlaro will provide further data on the benefits of this medicine from other studies, including a study in patients who have not been treated before.

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

The company that markets Ninlaro will provide the final data from the main study on the effects of the medicine on overall survival.

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

Other information about Ninlaro

The European Commission granted a marketing authorisation valid throughout the European Union for Ninlaro on 21 November 2016.

The full EPAR for Ninlaro can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Ninlaro, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The summary of the opinion of the Committee for Orphan Medicinal Products for Ninlaro can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/Rare disease designation.

This summary was last updated in 11-2016.