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Nexpovio (*selinexor*)

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

What is Nexpovio and what is it used for?

Nexpovio is a cancer medicine used to treat multiple myeloma (a cancer of the bone marrow). It is used together with two other medicines, bortezomib and dexamethasone, in adults who have received at least one previous treatment. It is also used together with dexamethasone in adults who have received at least four previous treatments and whose disease has worsened since the last treatment.

Nexpovio contains the active substance selinexor.

How is Nexpovio used?

Nexpovio can only be obtained with a prescription and treatment should be started and supervised by a doctor experienced in the treatment of multiple myeloma.

Nexpovio is available as tablets to be taken by mouth once a week when used in combination with bortezomib and dexamethasone or twice a week when used with only dexamethasone. The dose depends on the treatment combination used. Treatment can continue for as long as the patient benefits from it. Treatment may be stopped or the dose reduced if the patient has severe side effects or the disease gets worse.

For more information about using Nexpovio, see the package leaflet or contact your doctor or pharmacist.

How does Nexpovio work?

The active substance in Nexpovio, selinexor, blocks the action of a protein called exportin 1 (XPO1). XPO1 is found at high levels in many cancer cells, where it prevents the action of certain proteins that help stop cancer growth. By blocking XPO1, the medicine enhances the action of these proteins, causing the death of the cancer cells and thereby slowing progression of the disease.

What benefits of Nexpovio have been shown in studies?

A main study in 402 patients with multiple myeloma who had received at least one previous treatment found that Nexpovio given together with bortezomib and low-dose dexamethasone increased the time that patients lived without their disease getting worse. Patients receiving this combination lived for an

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average of 13.9 months without their disease getting worse, compared with 9.5 months for those who received a combination of only bortezomib and low-dose dexamethasone.

A second main study involving 83 patients with multiple myeloma showed that Nexpovio given together with low-dose dexamethasone was effective at reducing the cancer in patients whose disease had not improved after four previous treatments and had worsened after the last one. A quarter of patients (25.3%) had a reduction of their cancer with Nexpovio that lasted on average for 4 months.

What are the risks associated with Nexpovio?

The most common side effects with Nexpovio used together with bortezomib and dexamethasone (which may affect more than 3 in 10 people) are thrombocytopenia (low blood platelet counts), nausea (feeling sick), tiredness, anaemia (low red blood cell counts), decreased appetite, diarrhoea and peripheral neuropathy (nerve damage in the arms and legs).

The most common serious side effects with Nexpovio used together with bortezomib and dexamethasone (which may affect up to 2 in 10 people) are pneumonia (lung infection), cataract, sepsis (blood poisoning), diarrhoea, vomiting and anaemia.

The most common side effects with Nexpovio used together with dexamethasone (which may affect more than 3 in 10 people) are nausea, vomiting, decreased appetite, weight loss, diarrhoea, tiredness, thrombocytopenia, anaemia, low levels of white blood cells and hyponatraemia (low blood sodium levels).

The most common serious side effects with Nexpovio used together with dexamethasone (which may affect up to 1 in 10 people) are pneumonia, sepsis, thrombocytopenia, anaemia and damage to the kidneys.

For the full list of side effects and restrictions of Nexpovio, see the package leaflet.

Why is Nexpovio authorised in the EU?

Nexpovio used in combination with other cancer medicines has shown benefits in patients with multiple myeloma, both in those who have received at least four previous treatments and whose disease has come back, and in those who have received at least one previous treatment. In terms of safety, although Nexpovio has important side effects, they are generally considered manageable. The Agency therefore decided that Nexpovio's benefits are greater than its risks and it can be authorised for use in the EU.

Nexpovio 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 Nexpovio?

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

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

Other information about Nexpovio

Nexpovio received a conditional marketing authorisation valid throughout the EU on 26 March 2021. This was switched to a full marketing authorisation on 18 July 2022.

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

This overview was last updated in 07-2022.