

FACTSHEET

MYELOMA PATIENTS EUROPE

IXAZOMIB (Ninlaro®)

Edition: Myeloma Patients Europe (MPE)
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Myeloma
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FACTSHEET

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Myeloma Patients Europe (MPE) has developed a series of factsheets for patients and patient advocates, providing an overview of available treatment options for myeloma and covering some relevant topics related to the disease.

The factsheets cover important issues around the treatment, so that patients can feel safe and ask specific questions to their doctor.

For each of the available therapies, the following topics will be addressed:

- What is myeloma?
- What is the particular treatment?
- How does the treatment work?
- What are the benefits?
- What are the side effects?
- Who should not receive the treatment?
- How and when is the treatment given?

Access the following factsheets on:

- Amyloidosis
- Belantamab mafodotin
- Bortezomib
- Carfilzomib
- Daratumumab
- Elotuzumab
- Ixazomib
- Lenalidomide
- Panobinostat
- Pomalidomide
- Thalidomide
- Stem cell transplant

Myeloma treatment is constantly evolving and the factsheets will be updated regularly to reflect the latest developments.

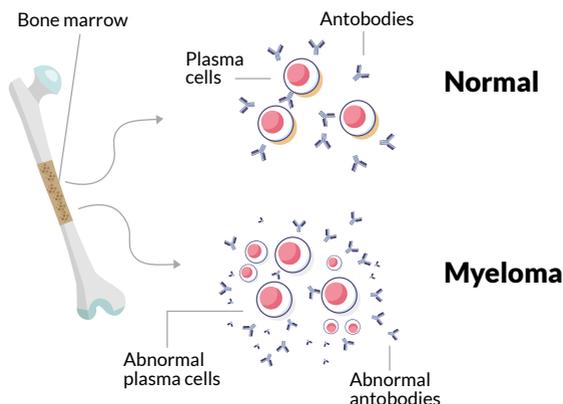
What is myeloma?

Myeloma is a rare cancer of the bone marrow. It is due to the formation of abnormal plasma cells, also called myeloma cells, which divide uncontrollably. Usually, plasma cells help the body to fight infections by making antibodies that recognise and attack germs. Myeloma affects multiple places in the body (this is why it is sometimes referred to as 'multiple myeloma') where bone marrow is normally active, such as the bones of the spine, pelvis, rib cage and the areas around the shoulders and hips.

Myeloma causes pain, anaemia (low red blood cells), fatigue, fractures, recurring infections, bruising and high blood calcium (hypercalcaemia). These symptoms require treatment; if the disease responds to therapy, there could be periods of time where symptoms subside and may not require any treatment. This cycle of remission and recurrence (relapse) often occurs several times. Many patients, particularly in relapse setting, will be on treatment for a long period of time to ensure that their myeloma is kept at bay.

Treatment may involve taking a combination of drugs that have been found to be more effective than single drugs. Myeloma generally cannot be cured, but survival rates are increasing in myeloma, due to the availability of new treatment and many patients are able to enjoy a good quality of life. A number of other new treatments have recently been approved or are under consideration for use following relapse, or for refractory myeloma.

Myeloma



What is ixazomib (Ninlaro®)?

In 2016 the European Medicines Agency (EMA) granted conditional marketing authorisation for ixazomib, the first oral proteasome inhibitor to treat adults with myeloma. It is indicated together with lenalidomide and dexamethasone in patients with relapsed or refractory myeloma who have received at least one prior treatment.

As multiple myeloma is considered a 'rare disease' because of the small number of patients with this disease, ixazomib was granted 'orphan drug designation' by the European Commission in 2011. An orphan drug designation is a status assigned to medicines developed for rare disease conditions that affect fewer than 5 patients per 10,000 inhabitants in the EU.

How does ixazomib work?

Ixazomib targets a part within cells called proteasomes. It works by blocking the actions of proteasomes. It belongs to the therapeutic class named the proteasome inhibitors which includes also bortezomib and carfilzomib. Proteasomes are large molecules found in cells of the body, and they are involved in the breakdown of damaged or unwanted proteins. Proteasome inhibitors temporarily block their function, stopping them from breaking down unwanted proteins. This causes proteins to build up to toxic levels, killing the cell. Myeloma cells rely more heavily on proteasomes than normal healthy cells; they are therefore much more sensitive to proteasome inhibitors.

What are the benefits of ixazomib?

Ixazomib has been proven in studies to help some patients live longer without their myeloma getting worse.

A clinical trial of 722 people whose myeloma had come back or stopped responding to prior therapy compared ixazomib with a placebo (a dummy treatment), both taken together with lenalidomide and dexamethasone. It measured the length of time a patient lived without their disease getting worse (progression-free survival)¹.

The combination of ixazomib plus lenalidomide and dexamethasone increased the length of progression-free survival by about six months: patients treated with ixazomib 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 improvement because further analysis of the data showed a reduced effect.

In a subsequent similar study involving 115 patients, many with advanced disease, those receiving ixazomib with lenalidomide (an immunomodulatory drug) and dexamethasone (an anti-inflammatory medicine) lived on average for 6.7 months without their disease getting worse compared with 4 months in those receiving placebo with lenalidomide and dexamethasone.

Ixazomib is currently being studied in clinical trials in relapsed and/or refractory myeloma, in newly diagnosed patients, and as maintenance therapy.

What are the side effects?

The most common side effects of ixazomib taken together with lenalidomide and dexamethasone (seen in more than 1 in 5 people) are:

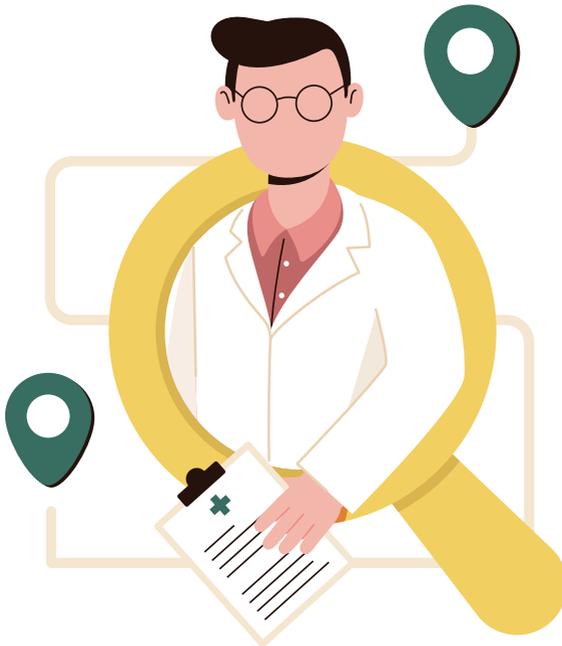
- diarrhoea
- constipation
- thrombocytopenia (low blood platelet counts)
- neutropenia (low levels of neutrophils, a type of white blood cells)
- peripheral neuropathy (nerve damage in the hands and feet causing tingling or numbness)
- nausea (feeling sick)
- peripheral oedema (swelling, especially of the ankles and feet)
- vomiting
- nose and throat infections

How and when is ixazomib given³?

Ixazomib is taken along with lenalidomide and dexamethasone. It is available as capsules (2.3, 3 and 4 mg) to be taken at least one hour before or two hours after food.

The initial recommended dose is 4 mg. This is taken once a week (on the same day of the week, day one, day eight and day fifteen every 28 days cycle) for 3 weeks in a row followed by a week with no ixazomib treatment. This 4-week 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.

People taking ixazomib should avoid taking strong CYP3A inducers (such as rifampin, phenytoin, carbamazepine, and St. John's Wort).



References

1. Avet-Loiseau H et al: Ixazomib significantly prolongs progression-free survival in high-risk relapsed/refractory patients with myeloma. *Blood*, December 2017; 130(24): 2610-2618.
2. Manufacturer's product information. <https://www.ninlaro.com/patient-information.pdf>
3. European Medicines Agency. Ninlaro (ixazomib) European public assessment report (EPAR) – last updated 10/2017 : <https://www.ema.europa.eu/en/medicines/human/EPAR/ninlaro>





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MPE is a network of European myeloma patient organisations. It supports national patient organisations to improve treatment and access for patients in their countries and helps inform and raise awareness on a European level through its educational programmes. Please note, this information does not replace the information provided by your doctor. If there is anything that is not clear to you, please always ask your clinical team.



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