Myeloma Patients Europe

FACTSHEET

MYELOMA PATIENTS EUROPE

LENALIDOMIDE (Revlimid®)

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FACTSHEET

MYELOMA PATIENTS EUROPE

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

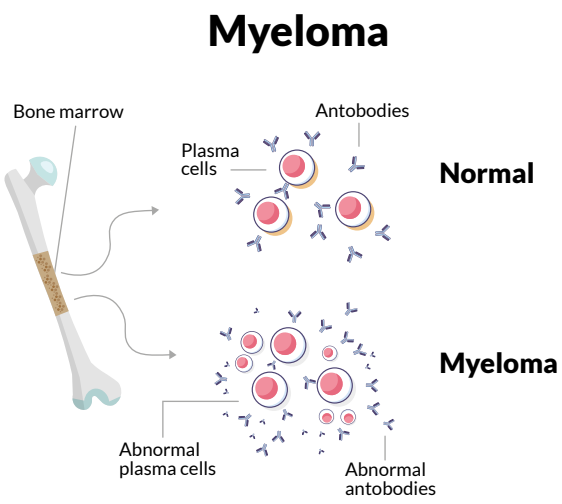
Myeloma treatment is constantly evolving and the factsheets will be updated regularly to reflect the latest developments.

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.



What is lenalidomide (Revlimid®)?

Lenalidomide is a cancer medicine approved in Europe in 2007 for the treatment of myeloma in the following situations[1]:

- Patients whose myeloma has been treated at least once previously. In these cases, lenalidomide is used in combination with dexamethasone (an anti-inflammatory medicine).
- Newly diagnosed myeloma patients (previously untreated), who are not eligible for an autologous stem cell transplantation, usually patients above the age of 70. It is used in combination with dexamethasone (an immunomodulatory medicine), or bortezomib and dexamethasone (RVd), or melphalan and prednisone (RMp).
- As monotherapy (by itself) for the maintenance treatment of adult patients with newly diagnosed myeloma who have undergone an autologous stem cell transplantation (the patient's bone marrow is cleared of cells and replaced by stem cells from the patient himself).

Lenalidomide is also a backbone treatment in many other approved combinations, such as[1]:

- In combination with elotuzumab and dexamethasone for adult patients who received at least one prior treatment (more information in the elotuzumab fact sheet)
- In combination with daratumumab and dexamethasone in newly diagnosed patients who are not eligible for autologous stem cell transplantation and in patients who have previously received at least one other treatment (more information in the Daratumumab fact sheet)
- In combination with carfilzomib and dexamethasone for the treatment of relapsed and refractory adult patients who have received at least one previous treatment (more information in the carfilzomib fact sheet)
- In combination with ixazomib and dexamethasone in relapsed/refractory patients who have received at least one prior treatment (more information in the ixazomib fact sheet)

As myeloma is considered a 'rare disease' because of the small number of patients with this disease, lenalidomide was granted 'orphan drug designation'

by the European Medicines Agency. An orphan drug designation is a status assigned to medicines developed for rare disease conditions that affect less than 5 patients per 10,000 inhabitants in the EU. Lenalidomide was withdrawn from the Community Register of designated orphan medicinal products in 2013 at the end of the 10-year period of market exclusivity.

How does lenalidomide work?

Lenalidomide belongs to a group of immunomodulating medicines used in the treatment of myeloma that also includes thalidomide and pomalidomide. They work by harnessing the immune system (the body's natural defence mechanism) to fight myeloma.

Lenalidomide blocks the development of abnormal cells, stimulates some cells of the immune system to destroy the abnormal cells, and prevents the growth of blood vessels within tumours (this limits the growth of the myeloma cancer cells).

What are the benefits of lenalidomide?

Lenalidomide as maintenance treatment has been proven in two main studies in 1,074 newly diagnosed patients who have had stem cell transplantation. Maintenance treatment is defined as a continuous treatment given to a patient after stem cell transplant with intent to prevent progression or worsening of their myeloma.

In the first study, patients taking lenalidomide as maintenance treatment after stem cell transplantation lived longer without their disease getting worse (41 months) than patients in the placebo group (23 months)2. In the second study, patients taking lenalidomide as maintenance also lived longer without their disease getting worse (46 months) than patients in the placebo group (27 months)[3].

In newly diagnosed multiple myeloma, lenalidomide has been studied in two main studies involving 2,082 patients. The first study compared lenalidomide with melphalan and prednisone with lenalidomide as maintenance vs. the same combination but without lenalidomide as maintenance (placebo). Patients taking lenalidomide (plus melphalan and prednisone) lived longer without their disease getting worse (31 months) than patients receiving placebo (14 months)[4]. In the second study, lenalidomide taken with low-dose dexamethasone was compared with the standard treatment of melphalan, prednisone and thalidomide. It took 26 months for the disease to get worse in patients taking lenalidomide plus dexamethasone, compared with 22 months for those on the standard treatment[5]

Who should not receive lenalidomide[6]?

Lenalidomide is a powerful teratogen, inducing high frequency of severe and life-threatening birth defects. It must never be used in pregnant women or in women who may become pregnant.

What is the Pregnancy Prevention Programme?

Lenalidomide must be prescribed and dispensed according to a special Pregnancy Prevention Programme for male and female patients put in place to prevent the exposure of unborn children to the medicine.

Women of childbearing potential must use one effective method of contraception for at least four weeks before the start of the treatment, during treatment, and until at least four weeks after any immunomodulatory drugs, this therapeutic class includes thalidomide, lenalidomide and pomalidomide, treatment and even in case of dose interruption unless the patient commits to absolute and continuous abstinence confirmed on a monthly basis. Because of the increased risk of venous thromboembolism in patients with multiple myeloma combined oral contraceptive pills are not recommended.

As lenalidomide is found in semen, as a precaution all male patients taking lenalidomide need to use a condom if engaged in sexual activity with a pregnant woman or a woman of childbearing potential not using effective contraception during treatment, during dose interruption and at least 7 days following discontinuation of treatment.

What are the side effects of lenalidomide[6]?

The most common side-effects of lenalidomide in the treatment of multiple myeloma (affecting more than 1 in 10 patients) are[1]:

- bronchitis (inflammation of the airways in the lung)
- nasopharyngitis (inflammation of the nose and the throat)
- gastroenteritis (inflammation of the stomach and intestines with diarrhoea and vomiting)
- upper respiratory tract infections (nose and throat infection)
- fatigue (tiredness)
- constipation
- diarrhoea
- muscle cramps
- rash
- back pain

- insomnia (difficulty sleeping)
- decreased appetite
- cough
- fever
- peripheral oedema (swelling of ankles and feet)
- peripheral neuropathy (nerve damage in the hands and feet)
- hypocalcaemia (low levels of calcium in the blood)
- weakness

And the following blood abnormalities are possible:

- leukopenia (low level of white blood cells - cells that help fight infection)
- neutropenia (low level of neutrophils - a type of white blood cell)
- anaemia (low level of red blood cells)
- thrombocytopenia (low level of blood platelets - components that help the blood to clot)

The most serious side effects with lenalidomide are: neutropenia, venous thromboembolism (blood clots in the veins) including pulmonary embolism (blood clots in the lungs), lung infections including pneumonia, hypotension (low blood pressure), dehydration, kidney failure, febrile neutropenia (neutropenia with fever), diarrhoea and anaemia.

How and when is lenalidomide given6?

Lenalidomide is available as capsules containing various amounts of the medicine (2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg and 25 mg) to be taken orally.

This drug is taken in repeated cycles of 28 days. Once a day for 21 days, at about the same time each day, followed by seven days without taking the medicine. In those patients who have received at least one prior therapy, the recommended dose is 25 mg of lenalidomide per day. Lenalidomide is given in combination with dexamethasone (an immunomodulatory medicine).

In newly diagnosed patients with multiple myeloma, the recommended dose is from 10 to 25 mg per day, depending on the other cancer medicines that the patient is taking.

The lenalidomide dose may be reduced or the treatment could be interrupted depending on the patient's condition, problems with their kidneys, severity of side effects, or the levels of neutrophils and platelets in the blood.

References

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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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