Myeloma Patients Europe

FACTSHEET

MYELOMA PATIENTS EUROPE

POMALIDOMIDE (Imnovid®)

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Edition: Myeloma Patients Europe (MPE)
Updated: November 2020

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FACT SHEET

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

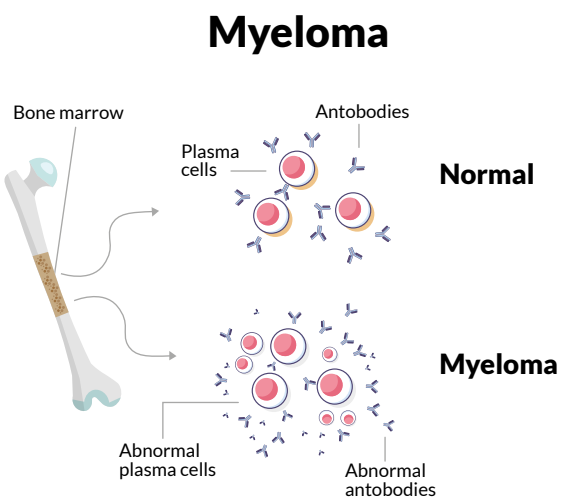
Myeloma treatment is constantly evolving and the factsheets will be updated regularly to reflect the latest developments.

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 pomalidomide (Imnovid®)?

Pomalidomide is an anti-cancer medicine approved in Europe since 2013 in combination with bortezomib (another cancer drug) and dexamethasone (an anti-inflammatory medicine) to treat adult myeloma patients who have received at least one prior treatment including lenalidomide and whose disease got worse after treatment[1].

Pomalidomide in combination with dexamethasone is also indicated for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior treatment regimes, including both lenalidomide and bortezomib and whose disease got worse after treatment[1].

As myeloma is considered a 'rare disease' because of the small number of patients with this disease, pomalidomide was granted 'orphan drug designation' by the European Commission in 2009. 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 pomalidomide work?

Pomalidomide is a type of biological therapy known as an immunomodulating agent, which includes similar drugs such as lenalidomide and thalidomide. It affects the activity of the immune system (the body's natural defence), by blocking the development of tumour cells, preventing the growth of blood vessels within tumours, and stimulating some of the specialised cells of the immune system to attach to the tumour cells.

What are the benefits of pomalidomide?

In an international study of 455 relapsed myeloma patients, whose disease did not get better or came back after previous treatments and who were treated with pomalidomide and low-dose dexamethasone, had significantly longer time until the disease got worse (progression-free survival) than patients treated with high-dose dexamethasone alone3. The disease worsened after 16 weeks on average in patients taking pomalidomide plus low-dose dexamethasone, compared with 8 weeks in those taking high-dose dexamethasone. Overall survival was also longer.

A further study included 559 patients with multiple myeloma who had received at least one treatment including lenalidomide, and whose disease got worse during or after their last treatment. Patients treated with pomalidomide, bortezomib and low-dose dexamethasone lived on average 11.2 months before their disease got worse, compared with 7.1 months for patients treated with bortezomib and low-dose dexamethasone[4].

What are the side effects with pomalidomide?

The most common side effects (which may affect more than 1 in 10 patients) are[2]:

- anaemia (low red blood cell counts)
- neutropenia (low white blood cell counts)
- thrombocytopenia (low platelet counts)
- fatigue (tiredness)
- fever
- peripheral oedema (swollen ankles and feet)
- peripheral neuropathy (tingling, pain and numbness in the hands and feet)
- pneumonia (infection of the lung)
- lower chest infection (bronchitis)
- pulmonary embolism (clot in a blood vessel in the lungs)
- flu
- acute kidney injury

You should see your doctor straight away if you have fever, sore throat or cough; bleeding or bruising without a cause (including nosebleeds); chest pain; leg pain and swelling; shortness of breath; or any swelling of face, lips, tongue and throat which may cause difficulty breathing.

Who should not receive pomalidomide2?

Pomalidomide can cause severe life-threatening birth defects. It must never be used in pregnant women or women who may become pregnant.

What is the Pregnancy Prevention Programme?

Pomalidomide 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 start of the treatment, during treatment, and until at least four weeks after 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 pomalidomide is found in semen, as a precaution all male patients taking pomalidomide need to use a condom if engaged in sexual activity with a pregnant women or a women of childbearing potential not using effective contraception during treatment, during dose interruption and at least 7 days following discontinuation of treatment.

How and when is pomalidomide given[1]?

Pomalidomide is available as capsules (1, 2, 3 and 4 mg) and is taken in the first two weeks of 3-week treatment cycles when given in combination with bortezomib and dexamethasone and in the first three weeks of 4-weeks treatment cycles when given in combination with dexamethasone only. The recommended starting dose is 4mg once a day, taken at the same time each day.

The pomalidomide dose may be reduced or the treatment could be interrupted if the disease gets worse or serious side effects occur.

References

1. European Medicines Agency. Imnovid (pomalidomide) European public assessment report (EPAR) – lay summary - last updated 04/2019: **https://www.ema.europa.eu/en/documents/overview/imnovid-epar-medicine-overview_en.pdf**

2. Patient Information Leaflet https://packageinserts.bms.com/medguide/medguide_pomalyst.pdf

3. Miguel, JS et al. Pomalidomide plus low-dose dexamethasone versus high-dose dexamethasone alone for patients with relapsed and refractory multiple myeloma (MM-003): a randomised, open-label, phase 3 trial. Lancet Oncol 2013; 14: 1055–66

4. Richardson PG et al. Pomalidomide, bortezomib and dexamethasone for patient with relapsed or refractory multiple myeloma previously treated with lenalidomide (OPTIMISMM): a randomised, open-label, phase 3 trials. Lancet Oncol 2019; 20(6): 781-794.

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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