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Imnovid[1] (*pomalidomide*)

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

What is Imnovid and what is it used for?

Imnovid is a cancer medicine used to treat multiple myeloma (a cancer of the bone marrow). It is used in combination with bortezomib (another cancer medicine) and dexamethasone (an anti-inflammatory medicine) in adults who have received at least one treatment including lenalidomide (another cancer medicine).

It is also used in combination with dexamethasone in adults who have received at least two prior therapies, including both lenalidomide and bortezomib, and whose disease has worsened.

Imnovid contains the active substance pomalidomide.

Multiple myeloma is rare, and Imnovid was designated an 'orphan medicine' (a medicine used in rare diseases) on 8 October 2009. Further information on the orphan designation can be found on ema.europa.eu/medicines/human/orphan-designations/EU309672.

How is Imnovid used?

Treatment with Imnovid must be started and supervised by a doctor experienced in treating multiple myeloma. The medicine can only be obtained with a prescription.

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

Treatment with Imnovid may need to be interrupted or stopped, or the dose reduced, if the disease gets worse or certain side effects occur. For more information about using Imnovid, see the package leaflet or contact your doctor or pharmacist.

[1] Previously known as Pomalidomide Celgene.

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How does Imnovid work?

The active substance in Imnovid, pomalidomide, is an immunomodulating agent. This means that it affects the activity of the immune system (the body's natural defences). Pomalidomide works in a number of ways in multiple myeloma, similarly to other immunomodulating medicines such as lenalidomide and thalidomide: it blocks the development of tumour cells, prevents the growth of blood vessels within tumours and also stimulates some specialised cells of the immune system to attack the tumour cells.

What benefits of Imnovid have been shown in studies?

Imnovid has been studied in one main study involving 455 adults with multiple myeloma whose disease did not get better or came back after previous treatments. Imnovid plus low-dose dexamethasone was more effective than high-dose dexamethasone alone at delaying the worsening of multiple myeloma. The disease worsened after 16 weeks on average in patients taking Imnovid plus low-dose dexamethasone, compared with 8 weeks in those taking high-dose dexamethasone.

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 Imnovid, 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.

What are the risks associated with Imnovid?

The most common side effects with Imnovid (which affect more than 1 in 10 patients), some of which can be serious, include anaemia (low red blood cell counts), neutropenia (low white blood cell count), tiredness, thrombocytopenia (low platelet counts), fever, peripheral oedema (swelling of the limbs due to fluid retention), peripheral neuropathy (nerve damage causing tingling, pain and numbness in the hands and feet) and infections including pneumonia (infection of the lungs). Serious side effects, which affect up to 1 in 10 patients, include blood disorders (such as neutropenia, anaemia and thrombocytopenia), lower respiratory tract infection (such as bronchitis or pneumonia), pulmonary embolism (clot in a blood vessel in the lungs), flu, and acute kidney injury.

Pomalidomide is expected to be harmful to the unborn child, causing severe and life-threatening birth defects. Therefore, Imnovid must not be used in women who are pregnant. It must not be used in women who could become pregnant, unless they take all the necessary steps to ensure that they are not pregnant before treatment and that they do not become pregnant during or soon after treatment. As the medicine can pass into semen, the medicine must also not be used in men who are unable to comply with the required contraceptive measures.

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

Why is Imnovid authorised in the EU?

The European Medicines Agency decided that Imnovid's benefits are greater than its risks and it can be authorised for use in the EU. The Agency concluded that Imnovid is effective at delaying the progression of multiple myeloma in patients whose disease has not got better or has come back after previous treatment, who have very limited treatment options. The Agency also noted that Imnovid's side effects were acceptable for these patients, with side effects similar to those of other medicines of this type.

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

The company that makes Imnovid will set up a pregnancy-prevention programme in each Member State. It will provide a letter and educational kits for healthcare workers, and brochures for patients, explaining that the medicine is expected to be harmful to the unborn child and detailing the steps needed to use the medicine safely. It will also supply cards for patients to ensure that all appropriate safety measures have been taken by each patient. Each Member State will also ensure that educational materials and patient cards are provided to prescribers and patients.

The company will also set up a registry of patients treated with Imnovid to monitor the side effects reported and whether the medicine is used for its approved indication and in compliance with the pregnancy-prevention programme. The medicine packs containing Imnovid capsules will carry a warning on the risk of severe birth defects.

The company will also provide final results from a study with Imnovid in combination with bortezomib and dexamethasone in patients with multiple myeloma who had received at least one treatment including lenalidomide, to confirm the medicine's effect on overall survival.

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

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

Other information about Imnovid

Imnovid received a marketing authorisation valid throughout the EU on 5 August 2013. Further information on Imnovid can be found on the Agency's website: ema.europa.eu/en/medicines/human/EPAR/imnovid-previously-pomalidomide-celgene

This overview was last updated in 04-2019.