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EPAR summary for the public

Imnovid[1]

pomalidomide

This is a summary of the European public assessment report (EPAR) for Imnovid. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Imnovid.

For practical information about using Imnovid, patients should read the package leaflet or contact their doctor or pharmacist.

What is Imnovid and what is it used for?

Imnovid is an anticancer medicine that contains the active substance pomalidomide. It is used in combination with dexamethasone (an anti-inflammatory medicine) to treat multiple myeloma (a cancer of the bone marrow). It is used in adults who have received at least two prior therapies, including both lenalidomide and bortezomib, and whose disease progressed after the last treatment.

Because the number of patients with multiple myeloma is low, the disease is considered 'rare', and Imnovid was designated an 'orphan medicine' (a medicine used in rare diseases) on 8 October 2009.

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) and is taken in 4-week treatment cycles. The recommended starting dose is 4 mg once a day, taken at the same time each day for the first 3 weeks of the cycle, followed by a week of no treatment. The recommended dose of dexamethasone is 40 mg once a day on days 1, 8, 15 and 22 of each cycle.

[1] Previously known as Pomalidomide Celgene.

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Treatment with Imnovid may need to be interrupted or stopped, or the dose reduced, if the disease gets worse or the patient experiences certain side effects. For further information, see the summary of product characteristics (also part of the EPAR).

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 agents such as lenalidomide and thalidomide: it blocks the development of tumour cells, prevents the growth of blood vessels within tumours and also stimulates some of the 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 respond to or came back after previous treatments. The study compared Imnovid plus low-dose dexamethasone with high-dose dexamethasone alone. The main measure of effectiveness was how long it took until the disease got worse.

Imnovid plus low-dose dexamethasone was more effective than high-dose dexamethasone alone at delaying the progression of multiple myeloma: on average, it took 16 weeks before the disease got worse in patients taking Imnovid plus low-dose dexamethasone, compared with 8 weeks in those taking high-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 were serious, include anaemia (low red-blood-cell counts), neutropenia (low white-blood-cell count), fatigue (tiredness), thrombocytopenia (low platelet counts), pyrexia (fever), peripheral oedema (swelling, especially of the ankles and feet), peripheral neuropathy (nerve damage causing tingling, pain and numbness in the hands and feet) and pneumonia (infection of the lungs). For the full list of all side effects reported with Imnovid, see the package leaflet.

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 of 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 be found in semen, the medicine must also not be used in male patients who are unable to comply with the required contraceptive measures. For the full list of restrictions, see the package leaflet.

Why is Imnovid approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Imnovid's benefits are greater than its risks and recommended that it be approved for use in the EU. The Committee concluded that Imnovid is effective at delaying the progression of multiple myeloma in patients whose disease does not respond to or comes back after previous treatment, who have very limited treatment options. The Committee also noted that the safety profile of Imnovid was considered 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?

A risk management plan has been developed to ensure that Imnovid is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Imnovid, including the appropriate precautions to be followed by healthcare professionals and patients.

In addition, 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 that need to be taken for the medicine to be used 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 in order to monitor the side effects reported and whether the medicine is used within 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.

Other information about Imnovid

The European Commission granted a marketing authorisation valid throughout the European Union for Pomalidomide Celgene on 5 August 2013. The name of the medicine was changed to Imnovid on 27 August 2013.

The full EPAR for Imnovid can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Imnovid, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The summary of the opinion of the Committee for Orphan Medicinal Products for Imnovid can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/Rare disease designation.

This summary was last updated in 09-2013.