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EPAR summary for the public

Thalidomide Celgene[1]

thalidomide

This is a summary of the European public assessment report (EPAR) for Thalidomide Celgene. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Thalidomide Celgene.

What is Thalidomide Celgene?

Thalidomide Celgene is a medicine containing the active substance thalidomide. It is available as capsules (50 mg).

What is Thalidomide Celgene used for?

Thalidomide Celgene is used to treat multiple myeloma (a cancer of the bone marrow) in combination with the cancer medicines melphalan and prednisone in patients who have not been treated for multiple myeloma before. It is used in patients aged over 65 years, and in younger patients if they cannot be treated with high-dose chemotherapy (anticancer treatments).

Thalidomide Celgene must be prescribed and dispensed according to a special programme put in place to prevent the exposure of unborn children to the medicine.

Because the number of patients with multiple myeloma is low, the disease is considered 'rare', and Thalidomide Celgene was designated an 'orphan medicine' (a medicine used in rare diseases) on 20 November 2001.

The medicine can only be obtained with a prescription.

[1] Previously known as Thalidomide Pharmion.

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How is Thalidomide Celgene used?

Treatment with Thalidomide Celgene must be started and monitored under the supervision of a doctor who is skilled in using medicines that modulate the immune system or cancer medicines. The doctor must also understand the risks of thalidomide and the ways in which the use of the medicine must be monitored.

The recommended dose of Thalidomide Celgene is 200 mg (4 capsules) a day, taken at the same time, preferably at bedtime. In patients over 75 years of age a starting dose of 100 mg (2 capsules) a day is recommended. Thalidomide Celgene can be used for a maximum of 12 treatment cycles, with each cycle lasting six weeks. The doctor may delay, reduce or stop doses if the patient experiences certain side effects, including blood clots, nerve damage, rash, low heart rate, fainting or sleepiness. Each patient should also receive an anticoagulant (a medicine to prevent the formation of blood clots) for at least the first five months of treatment, after careful assessment of the patient's individual risk.

How does Thalidomide Celgene work?

The active substance in Thalidomide Celgene, thalidomide, is thought to work by blocking the development of cancer cells, and by stimulating some of the specialised cells of the immune system (the body's defence mechanism) to attack the cancer cells. This can help to slow down the progression of multiple myeloma.

How has Thalidomide Celgene been studied?

Thalidomide Celgene was studied in one main study involving 447 patients with multiple myeloma. The study included patients over 65 years of age, as well as younger patients who could not be treated with high-dose chemotherapy. The study compared the effect of melphalan and prednisone, with or without Thalidomide Celgene, on survival times.

The company also presented the results of a study looking at the combination of Thalidomide Celgene and dexamethasone as 'induction' treatment for multiple myeloma for use before high-dose chemotherapy. However, it withdrew this application during the initial assessment of the medicine.

What benefit has Thalidomide Celgene shown during the studies?

Survival times were longer in the patients receiving Thalidomide Celgene in addition to melphalan and prednisone: patients receiving melphalan and prednisone survived for an average of 33.2 months from the start of the study, compared with 51.6 months when the treatment also included Thalidomide Celgene.

What is the risk associated with Thalidomide Celgene?

Most patients taking thalidomide experience side effects. The most common side effects with Thalidomide Celgene used together with melphalan and prednisone (seen in more than 1 patient in 10) are neutropenia (low levels of neutrophils, a type of white blood cell), leucopenia (low white blood cell counts), anaemia (low red blood cell counts), lymphopenia (low levels of lymphocytes, another type of white blood cell), thrombocytopenia (low levels of platelets in the blood), peripheral neuropathy (nerve damage causing tingling, pain and numbness in the hands and feet), tremor (shaking), dizziness, paraesthesia (unusual sensations like pins and needles), dysaesthesia (reduced sense of touch), somnolence (sleepiness), constipation and peripheral oedema (swelling, usually in the legs). For the full list of all side effects reported with Thalidomide Celgene, see the package leaflet.

Thalidomide is a powerful human 'teratogen', meaning that it has a harmful effect on the unborn child, causing severe and life-threatening birth defects. The strict conditions put in place to prevent pregnancies and the exposure of unborn children to thalidomide must be met by all men and women taking the medicine.

Thalidomide Celgene must never be used by the following groups:

- women who are pregnant;
- 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;
- patients who are unable to follow or to comply with the requirement to use contraceptives.

For the full list of restrictions, see the package leaflet.

Why has Thalidomide Celgene been approved?

The CHMP concluded that, provided that very strict measures are put in place to avoid exposure of unborn children to thalidomide, Thalidomide Celgene's benefits are greater than its risks and recommended that it be given marketing authorisation.

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

A risk management plan has been developed to ensure that Thalidomide Celgene 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 Thalidomide Celgene, including the appropriate precautions to be followed by healthcare professionals and patients.

In addition, the company that markets Thalidomide Celgene 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, 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 are taken by each patient. Each Member State will also ensure that educational materials and patient cards are provided as necessary to prescribers and patients.

The company will also collect information on whether the medicine is used outside its approved indication. The boxes containing Thalidomide Celgene capsules will include a warning stating that thalidomide is harmful to the unborn child.

Other information about Thalidomide Celgene

The European Commission granted a marketing authorisation valid throughout the European Union for Thalidomide Pharmion on 16 April 2008. The name of the medicine was changed to Thalidomide Celgene on 22 October 2008.

The full EPAR for Thalidomide Celgene 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 Thalidomide Celgene, 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 Thalidomide Celgene can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/Rare disease designation.

This summary was last updated in 11-2015.