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Thalidomide BMS[1]

thalidomide

What is Thalidomide BMS and what is it used for?

Thalidomide BMS 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 65 years or over, and in younger patients if they cannot be treated with high-dose chemotherapy.

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

It contains the active substance thalidomide.

How is Thalidomide BMS used?

Thalidomide BMS can only be obtained with a prescription and treatment must be started and monitored under the supervision of a doctor skilled in using medicines that modulate the immune system or medicines to treat cancer. The doctor must also understand the risks of thalidomide and how its use must be monitored.

Thalidomide BMS is available as capsules (50 mg). The recommended dose 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 BMS can be used for a maximum of 12 treatment cycles, with each cycle lasting 6 weeks. The doctor may delay, reduce or stop doses if the patient gets certain side effects, including blood clots, nerve damage, rash, low heart rate, fainting or sleepiness.

For more information about using Thalidomide BMS, see the package leaflet or contact your doctor or pharmacist.

How does Thalidomide BMS work?

The active substance in Thalidomide BMS, 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

[1] Initially known as Thalidomide Pharmion and subsequently as Thalidomide Celgene.

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natural defences) to attack the cancer cells. This can help to slow down the progression of multiple myeloma.

What benefits of Thalidomide BMS have been shown in studies?

Thalidomide BMS increased the time patients lived 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 BMS. Patients receiving melphalan and prednisone lived for an average of 33.2 months from the start of the study, compared with 51.6 months when the treatment also included Thalidomide BMS.

The company also presented the results of a study looking at the combination of Thalidomide BMS 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 are the risks associated with Thalidomide BMS?

Most patients taking thalidomide get side effects. The most common side effects with Thalidomide BMS 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), sleepiness, constipation and peripheral oedema (swelling, usually in the legs). For the full list of side effects reported with Thalidomide BMS, see the package leaflet.

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

Thalidomide BMS 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 is Thalidomide BMS authorised in the EU?

Thalidomide BMS, in combination with melphalan and prednisone, has been shown to prolong the life of patients with multiple myeloma. The European Medicines Agency concluded that, provided that very strict measures are put in place to avoid exposure of unborn children to thalidomide, Thalidomide BMS's benefits are greater than its risks and it can be authorised for use in the EU.

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

The company that markets Thalidomide BMS will set up a pregnancy prevention programme in each Member State. It will provide 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 BMS capsules will include a warning that thalidomide is harmful to the unborn child.

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

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

Other information about Thalidomide BMS

Thalidomide Pharmion received a marketing authorisation valid throughout the EU on 16 April 2008. The name of the medicine was changed to Thalidomide Celgene on 22 October 2008 and to Thalidomide BMS on 4 November 2021.

Further information on Thalidomide BMS can be found on the Agency's website:ema.europa.eu/medicines/human/EPAR/thalidomide-bms. .

This overview was last updated in 01-2022.