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Thalidomide Lipomed (*thalidomide*)

An overview of Thalidomide Lipomed and why it is authorised in the EU

What is Thalidomide Lipomed and what is it used for?

Thalidomide Lipomed is a medicine 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.

It contains the active substance thalidomide.

Thalidomide Lipomed is a 'hybrid medicine'. This means that it is similar to a 'reference medicine' containing the same active substance, but with certain differences. While the reference medicine, Thalidomide BMS, is a 50 mg capsule, Thalidomide Lipomed is a 100 mg tablet.

How is Thalidomide Lipomed used?

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

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 Lipomed is available as tablets (100 mg). The recommended dose is 200 mg (2 tablets) a day, taken at the same time, preferably at bedtime. In patients over 75 years of age, a starting dose of 100 mg (1 tablet) a day is recommended. Thalidomide Lipomed 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 Lipomed, see the package leaflet or contact your doctor or pharmacist.

How does Thalidomide Lipomed work?

The active substance in Thalidomide Lipomed, thalidomide, is thought to work by blocking the development of cancer cells, and by stimulating specialised cells of the immune system (the body's

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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 Lipomed have been shown in studies?

The company provided information from the published literature on the benefits and risks of thalidomide in the approved uses.

As for every medicine, the company provided studies on the quality of Thalidomide Lipomed. It also carried out a study to show bioequivalence with Thalidomide BMS. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect. Although the study did not find that the medicines were bioequivalent, the difference was very small and did not affect how effective Thalidomide Lipomed is or its safety profile.

What are the risks associated with Thalidomide Lipomed?

Most patients taking thalidomide get side effects. The most common side effects with Thalidomide Lipomed 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 in arms and legs, causing pain or numbness, burning and tingling), tremor (shaking), dizziness, paraesthesia (sensations like numbness, tingling, pins and needles), dysaesthesia (unpleasant and abnormal feeling when touched), sleepiness, constipation and peripheral oedema (swelling especially of the ankles and feet). For the full list of side effects reported with Thalidomide Lipomed, 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 Lipomed 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;
- male 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 Lipomed authorised in the EU?

The European Medicines Agency concluded that although Thalidomide Lipomed was not shown to be bioequivalent to Thalidomide BMS, the difference is small and does not lead to a change in effects or result in safety issues. Therefore the Agency decided that, as for Thalidomide BMS, the benefit of Thalidomide Lipomed outweighs its identified risk and it can be authorised for use in the EU.

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

The company that markets Thalidomide Lipomed 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 Lipomed tablets 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 Lipomed have also been included in the summary of product characteristics and the package leaflet.

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

Other information about Thalidomide Lipomed

Thalidomide Lipomed received a marketing authorisation valid throughout the EU on 19 September 2022.

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

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