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EPAR summary for the public

Zinbryta

daclizumab

This is a summary of the European public assessment report (EPAR) for Zinbryta. 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 Zinbryta.

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

What is Zinbryta and what is it used for?

Zinbryta is a medicine used to treat adults with the relapsing forms of multiple sclerosis. Multiple sclerosis is a disease in which inflammation damages the protective sheath around the nerve cells in the brain and spinal cord. Relapsing means that the patient has flare-ups of the symptoms.

Zinbryta contains the active substance daclizumab.

How is Zinbryta used?

Zinbryta can only be obtained with a prescription and treatment should be started by a doctor with experience in managing multiple sclerosis. The recommended dose is 150 mg once a month by injection under the skin. Patients should be trained to give themselves the injection using either a prefilled syringe or an injection pen device. For further information, see the package leaflet.

How does Zinbryta work?

In multiple sclerosis, the body's immune (defence) system incorrectly attacks and damages the protective sheath around the nerve cells in the central nervous system (the brain and spinal cord). The active substance in Zinbryta, daclizumab, is a monoclonal antibody that attaches to T cells. These cells form part of the body's immune system and they are activated by interleukin-2, a signalling protein in the body. By attaching to the T cells, daclizumab blocks interleukin-2, so preventing T cells from

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attacking and damaging nerve cells. Daclizumab may also have other effects that reduce the immune system's damaging effects on nerve cells.

What benefits of Zinbryta have been shown in studies?

Zinbryta has been found effective for treating relapsing multiple sclerosis in two main studies involving over 2,400 patients.

In one study involving 600 patients, Zinbryta was found to be more effective than placebo (a dummy treatment) at reducing relapses of the condition. Patients receiving Zinbryta 150 mg every 4 weeks had on average 0.21 relapses over a year compared with 0.46 in those receiving placebo.

In another study involving 1,841 patients, patients receiving Zinbryta 150 mg every 4 weeks had on average 0.22 relapses over a year compared with 0.39 in those receiving interferon beta-1a, another medicine used for multiple sclerosis.

What are the risks associated with Zinbryta?

The most common side effects with Zinbryta (which may affect more than 1 in 100 people) are rash, increased liver enzymes in the blood, depression, inflamed and sore nose and throat, influenza and upper respiratory tract infection such as colds and lymphadenopathy (swollen glands). The most common serious side effects of Zinbryta are liver damage and severe skin reactions. For the full list of restrictions and of all side effects reported with Zinbryta, see the package leaflet.

Why is Zinbryta approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Zinbryta's benefits are greater than its risks and recommended that it be approved for use in the EU. Zinbryta has been found to be effective in studies carried out over up to 3 years. Zinbryta works in a different way to existing treatments and has the advantage that it is given just once a month. Treatment is associated with adverse effects on the liver and an increased risk of infections but the CHMP considered these could be managed with regular monitoring.

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

The company that markets Zinbryta will issue educational materials for healthcare professionals and for patients about liver damage and how to prevent or reduce the damage.

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

Other information about Zinbryta

The European Commission granted a marketing authorisation valid throughout the European Union for Zinbryta on 1 July 2016.

The full EPAR for Zinbryta 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 Zinbryta, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 07-2016.