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EPAR summary for the public

Trobalt

retigabine

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

What is Trobalt?

Trobalt is a medicine that contains the active substance retigabine. It is available as tablets (50, 100, 200, 300 and 400 mg).

What is Trobalt used for?

Trobalt is used in combination with other anti-epileptic medicines to treat adults with drug-resistant partial-onset seizures (epileptic fits) that cannot be treated with other combinations of medicines. This is a type of epilepsy where too much electrical activity in one part of the brain causes symptoms such as sudden, jerky movements of one part of the body, distorted hearing, sense of smell or vision, numbness or a sudden sense of fear. It is used in epilepsy with or without 'secondary generalisation' (when the excessive electrical activity reaches the whole brain).

The medicine can only be obtained with a prescription.

How is Trobalt used?

Treatment with Trobalt starts with one 100 mg tablet three times a day for one week; the dose is then increased weekly by 50 mg per dose according to the patient's response. The recommended maintenance dose is between 600 mg a day and a maximum of 1,200 mg a day.

Lower doses should be used in older patients and in patients with moderate or severe liver or kidney problems. For more information on how to use Trobalt, including detailed recommendations for different patients groups, see the summary of product characteristics (also part of the EPAR).

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How does Trobalt work?

The active substance in Trobalt, retigabine, is an anti-epileptic medicine. Epilepsy is caused by excessive electrical activity in the nerve cells of the brain. Trobalt has an effect on the potassium channels located on the nerve cells of the brain. These are pores that let potassium move in and out of the cell and play a role in terminating electrical impulses. Trobalt acts by keeping the potassium channels open. This will stop further transmission of electrical impulses thereby preventing epileptic seizures.

How has Trobalt been studied?

Trobalt has been compared with placebo (a dummy treatment) in three main studies involving a total of 1,244 patients whose seizures were not adequately controlled with other anti-epileptic medicines. Trobalt at a maintenance dose of 600, 900 or 1,200 mg a day or placebo was taken for 8 weeks in the first study and 12 weeks in the other two studies. In the first study, the main measure of effectiveness was the change in the number of seizures per month. In the other two studies, the main measure of effectiveness was the number of patients whose number of seizures was at least halved.

What benefit has Trobalt shown during the studies?

Trobalt was more effective than placebo in reducing the number of seizures. In the first study, Trobalt at 900 mg a day and 1,200 mg a day was more effective than placebo and reduced the number of seizures per month by 29% and 35% respectively. This compared with a reduction of 13% in the placebo group. The effect of Trobalt at 600 mg a day was inconclusive in this study. In the second study, seizures were at least halved in 39% (61 out of 158 patients) of the patients on 600 mg Trobalt a day and in 47% (70 out of 149 patients) of the patients on 900 mg a day, compared with 19% (31 out of 164) of the patients on placebo. In the third study, seizures were at least halved in 56% (66 out of 119 patients) of the patients taking 1,200 mg Trobalt a day, compared with 23% (31 out of 137) of the patients on placebo.

What is the risk associated with Trobalt?

The most common side effects with Trobalt (seen in more than 1 patient in 10) are dizziness, somnolence (sleepiness), fatigue (tiredness) as well as pigment changes (discolouration) of parts of the eye (including the retina, the light sensitive membrane at the back of the eye) and discolouration of the nails, lips and skin, which have been reported after several years of treatment. For the full list of all side effects reported with Trobalt, see the package leaflet.

Trobalt must not be used in people who are hypersensitive (allergic) to retigabine or any of the other ingredients.

Why has Trobalt been approved?

The CHMP decided that the benefits of Trobalt are greater than its risks and recommended that it be given marketing authorisation. The CHMP noted that Trobalt is effective at reducing the number of seizures. However, because of the risk of retinal discolouration, which could possibly result in impaired vision, the CHMP concluded that the use of Trobalt should be restricted only to those patients for whom other anti-epileptic medicines have proved inadequate or have not been tolerated.

What measures are being taken to ensure the safe use of Trobalt?

The company that makes Trobalt must ensure that doctors who are expected to prescribe Trobalt receive an information pack containing important safety information, including information on the risk of pigment changes in the eye and discolouration of the nails, lips and skin, and on the need for a full eye examination at the start of treatment and at least every 6 months during treatment. It will also include information on some less common side effects that have been reported with the medicine, such as problems with passing urine, prolonged QT interval (an alteration of the electrical activity of the heart) and hallucinations (seeing or hearing things that are not there).

Other information about Trobalt

The European Commission granted a marketing authorisation valid throughout the European Union for Trobalt on 28 March 2011.

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

This summary was last updated in 07-2013.