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Zeposia (*ozanimod*)

An overview of Zeposia and why it is authorised in the EU

What is Zeposia and what is it used for?

Zeposia is a medicine used to treat adults with the following diseases:

- relapsing-remitting multiple sclerosis (RRMS). Multiple sclerosis is a disease in which the immune system (the body's defences) attacks and damages the protective insulation around the nerves and the nerves themselves in the brain and spinal cord. In RRMS, the patient has flare-ups (relapses) followed by periods with milder or no symptoms (remission). Zeposia is used in patients with active disease, which means that patients have relapses or signs of active inflammation on scans;
- ulcerative colitis, a disease causing inflammation and ulcers in the lining of the gut, when the disease is moderately to severely active. Zeposia is used when standard treatment or biological agents (medicines made by cells grown in a laboratory) have not worked well enough or cannot be used by the patient.

Zeposia contains the active substance ozanimod.

How is Zeposia used?

Zeposia can only be obtained with a prescription and treatment should be started and supervised by a doctor experienced in the management of multiple sclerosis or ulcerative colitis.

It is available as capsules of different strengths and should be taken once a day. To reduce the risk of side effects on the heart, the dose should be built up slowly when starting treatment or after treatment has been interrupted. The starting dose is one 0.23 mg capsule a day for the first 4 days; patients should then take one 0.46 mg capsule a day for 3 days (on days 5, 6 and 7), and then one 0.92 mg capsule daily from day 8 onward.

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

How does Zeposia work?

The active substance in Zeposia, ozanimod, blocks the action of sphingosine-1-phosphate receptors on lymphocytes (cells of the immune system that can attack the body's own tissues in diseases such as multiple sclerosis or ulcerative colitis). By attaching to these receptors, ozanimod stops lymphocytes

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from travelling from the lymph nodes towards the brain, spinal cord or intestine, thus limiting the damage they cause in multiple sclerosis and ulcerative colitis.

What benefits of Zeposia have been shown in studies?

RRMS

Zeposia was shown to be effective at reducing the number of relapses in two main studies involving a total of 2,666 patients with RRMS.

In the first study lasting over one year, the average number of relapses per year in patients treated with the standard dose of Zeposia was about half that in patients treated with another medicine, interferon beta-1a (0.18 versus 0.35 relapses).

In the second study, which lasted two years, patients treated with the standard dose of Zeposia had on average 0.17 relapses per year, compared with 0.28 for patients given interferon beta-1a.

Ulcerative colitis

One main study showed that Zeposia, taken together with aminosalicylates (anti-inflammatory medicines) and/or corticosteroids, was more effective than placebo (a dummy treatment) in producing or maintaining remission (a period when the disease is not active or causing noticeable symptoms) in adults with moderate to severe ulcerative colitis for whom standard treatment or treatment with biological agents did not work well enough or could not be used.

The study was divided into two parts lasting one year in total. One part involved 645 patients and studied the effect of initial (induction) treatment with Zeposia for 10 weeks. The other part involved 457 patients who had responded to the 10-week induction treatment and studied the effect of Zeposia as maintenance treatment for 42 weeks.

After induction treatment, around 18% (79 of 429) of the patients taking Zeposia had achieved remission compared with around 6% (13 of 216) of the patients taking placebo. After maintenance treatment, around 37% (85 of 230) of the patients taking Zeposia were in remission compared with 19% (42 of 227) of the patients taking placebo.

What are the risks associated with Zeposia?

The most common side effects with Zeposia are nasopharyngitis (inflammation of the nose and throat), which may affect more than 1 in 10 people, and increased levels of liver enzymes (a sign of liver problems), which may affect up to 1 in 10 people; around 1 person in 100 had to stop treatment during the studies because of increases in liver enzyme levels. For the full list of side effects of Zeposia, see the package leaflet.

Zeposia must not be used in patients with severe liver disorders, severe active infections, cancer or weakened immune system. It must not be used in patients with certain heart conditions or who have recently had a stroke, a heart attack or other heart problems. It must also not be used in pregnant women or women who can become pregnant and are not using effective contraception. For the full list of restrictions, see the package leaflet.

Why is Zeposia authorised in the EU?

Zeposia was shown to be effective at reducing the number of relapses in patients with relapsing-remitting multiple sclerosis and at improving symptoms in patients with ulcerative colitis in the short

and long term. Its side effects are comparable to those of other medicines that work in a similar way and are considered manageable with appropriate treatment.

The European Medicines Agency, therefore, decided that Zeposia'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 Zeposia?

The company that markets Zeposia will provide educational materials for doctors and a guide for patients and their carers with important safety information about the medicine, its risks and its conditions for use. A reminder card will also be given to women who can become pregnant with important information on the need to use effective contraception during treatment with Zeposia.

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

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

Other information about Zeposia

Zeposia received a marketing authorisation valid throughout the EU on 20 May 2020.

Further information on Zeposia can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/zeposia.

This overview was last updated in 11-2021.