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Zeposia® (active substance: ozanimod as ozanimod hydrochloride)

First authorisation in Switzerland: 11 August 2020

Medicinal product (hard gelatin capsules) for the treatment of adult patients with relapsing-remitting multiple sclerosis.

About the medicine

The medicinal product Zeposia, with the active substance ozanimod, is supplied as a hard gelatin capsule. It has been authorised for the treatment of adult patients with relapsing-remitting multiple sclerosis.

Multiple sclerosis is a chronic disease that affects the central nervous system, i.e. the brain and spinal cord. In this disease, the body's immune system attacks the protective sheath surrounding nerve cells, potentially leading to neurological problems and severe disability. In relapsing-remitting multiple sclerosis, the patient experiences a period of worsening symptoms, called a relapse, followed by a period of decreasing symptoms, called remission.

Multiple sclerosis affects millions of people worldwide, including about 8,000 in Switzerland, with rates increasing.

Mode of action

Ozanimod, the active substance in Zeposia, is a sphingosine 1-phosphate receptor modulator. Ozanimod works by retaining lymphocytes, disease-fighting white blood cells, within the tissues that create them, such as lymph nodes and the spleen.

It is believed that ozanimod is effective because the lymphocytes held back in the lymphatic tissue are unable to cross the blood-brain barrier into the central nervous system.

By preventing lymphocytes from reaching the central nervous system, ozanimod reduces the inflammatory reactions that damage the brain and spinal cord.

Use

The recommended dosage of Zeposia is 0.92 mg once daily. This is the full dose and must be reached only after a step-up regimen. On days 1 to 4 of treatment, patients are given a dose of 0.23 mg once daily. The dose is then increased to 0.46 mg once daily on days 5 to 7. The recommended maintenance dose of 0.92 mg once daily begins on day 8. Taking

Zeposia without this gradual increase in dosage can lead to a reduction in heart rate.

Despite the gradually increasing dosage, Zeposia may still cause a reduced heart rate, known as bradycardia, at the beginning of treatment. It is recommended that at least patients with a history of heart conditions, including heart attack or heart failure, are monitored for 6 hours after the first dose.

Efficacy

The efficacy of Zeposia, with the active substance ozanimod, was investigated in two studies. The first study, SUNBEAM, with 1,346 patients, lasted one year. The second, RADIANCE, with 1,313 patients, lasted two years.

Both studies compared the active substance ozanimod with a known multiple sclerosis treatment called interferon beta-1a. In these studies, participants were monitored for relapses and the number and size of lesions in the brain and spinal cord. Lesions are areas of damage which become visible on MRI images as the disease progresses.

The average number of relapses was significantly lower in participants who received the active substance ozanimod than in those who received the standard treatment. The number and size of lesions were also smaller in the ozanimod group. However, there was no significant difference in the rate of progression of disability between those treated with ozanimod and those treated with interferon beta-1a.

Precautions, undesirable effects & risks

Zeposia must not be used if the patient has a hypersensitivity to the active substance ozanimod or any other substance in the medicine.

Treatment must not be given to patients who, in the previous 6 months, have had a heart attack, unstable angina pectoris (sensation of constriction in the chest), a stroke, a transient ischaemic attack (temporary impairment of circulation in the brain with neurological deficits) or certain types of heart failure.

Treatment should also not be initiated in patients with severe untreated sleep apnoea, patients receiving immunosuppressive treatment, patients with serious active infections or active chronic infections (hepatitis or tuberculosis), cancer, serious liver problems or macular oedema (accumulation of fluid in the central region of the retina) or during pregnancy.

Treatment with Zeposia may cause a decreased heart rate. Before treatment with Zeposia is started, any previously unknown heart conditions should be ruled out in all patients by means of an electrocardiogram (ECG)

The most common side effects were swelling of the nose and throat and increased levels of liver enzymes in the blood.

All precautions, risks and other possible undesirable effects are listed in the Information for healthcare professionals.

Why the medicine has been authorised

It was demonstrated that Zeposia, with the active substance ozanimod, effectively reduced the number of relapses and the number and size of lesions in the brain and bone marrow compared with treatment with interferon beta-1a.

During treatment with Zeposia there is a potential risk of, among other things, a reduction in heart rate and liver damage.

Taking all the precautions into account, and based on the available data, the benefits of Zeposia outweigh the risks. Swissmedic has therefore authorised the medicine Zeposia with the active substance ozanimod for use in Switzerland.

Further information on the medicinal product

Information for patients (package leaflet):
Information for patients Zeposia®

Information for healthcare professionals:
Information for healthcare professionals Zeposia®

Healthcare professionals (doctors, pharmacists and others) can answer any further questions.

This information is correct as at the date above. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

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