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Ponvory® (active substance: ponesimod)

First authorisation in Switzerland: 16 November 2021

Medicinal product (film-coated tablets) for the treatment of adults with relapsing forms of multiple sclerosis

About the medicinal product

The medicinal product Ponvory contains the active substance ponesimod. It is used to treat adult patients who have active, relapsing-remitting forms of multiple sclerosis (RRMS). Ponvory is taken orally in the form of film-coated tablets.

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 and destroys it, potentially leading to neurological problems and severe disability. In relapsing-remitting multiple sclerosis, there is a period of worsening symptoms, called a relapse, followed by a period of decreasing symptoms, called remission. Multiple sclerosis affects millions of people worldwide. Around 15,000 people in Switzerland are currently affected.

Mode of action

Ponesimod, the active substance in Ponvory, reduces the number of lymphocytes (a type of white blood cell) that pass into the central nervous system in circulating blood.

The mechanism of action of ponesimod retains the lymphocytes in the lymphoid organs (lymph nodes), meaning that fewer lymphocytes are available to attack the protective sheath surrounding the nerves in the brain and spinal cord.

This reduces the inflammatory reactions and nerve damage caused by multiple sclerosis (MS) and ultimately also the number of relapses.

Use

Ponvory, with the active substance ponesimod, is a prescription-only medicine.

It is available as film-coated tablets with the dosage strengths 2 mg, 3 mg, 4 mg, 5 mg, 6 mg, 7 mg, 8 mg, 9 mg, 10 mg and 20 mg.

The starting dose is 1 film-coated tablet containing 2 mg once a day. At the start of treatment with Ponvory the heart rate may slow temporarily and cardiac arrhythmias may occur. The daily dose is therefore in-

creased gradually on the doctor's instructions until the recommended therapeutic dose of 20 mg ponesimod daily is reached.

The cardiac activity of patients with certain heart diseases should be monitored by the doctor for 4 hours after the first dose has been taken.

Only one film-coated tablet should be taken each day. The film-coated tablet can be taken before or after a meal. The film-coated tablet should always be taken at the same time of day so that it is not forgotten.

Efficacy

The efficacy of Ponvory was investigated in a randomised double-blind pivotal[1] study involving 1,133 patients with multiple sclerosis.
This study compared the active substance ponesimod with a known multiple sclerosis treatment called teriflunomide. The number of relapses experienced by the study subjects was investigated, as was 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 age of the patients was 37 years. 65% of the study subjects were female.

The pivotal study lasted 108 weeks, including the 14-day phase needed to gradually increase the daily dose of ponesimod to 20 mg per day. After the study had ended, the patients were monitored for 30 days for safety reasons.

The study showed that the number of relapses in patients treated with ponesimod was approx. 30% lower than in those treated with teriflunomide. The number and size of lesions were also smaller in the ponesimod group. However, there was no significant difference in the rate of progression of disability between those treated with teriflunomide and those treated with ponesimod.

Precautions, undesirable effects & risks

Ponvory must not be used in those who are hypersensitive to the active substance or any of the excipients.

The doctor should record an electrocardiogram (ECG) of all patients to examine their cardiac activity before treatment with Ponvory is started.

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.

Ponvory must not be given to patients with impaired liver function.

The medicinal product Ponvory must not be given to patients who are taking medication to suppress their immune system, who have a serious active infection or who have cancer.

Ponvory must not be given to women who are not using contraception.

[1] A pivotal study is one that is relevant for authorisation

Like all medicines, Ponvory can produce side effects, although not necessarily in everyone.

Frequent side effects (affecting more than 1 in 100 but fewer than 1 in 10 users) include nasopharyngitis (combined inflammation of the nose and throat), infection of the upper respiratory tract and increased liver enzyme levels.

All precautions, risks and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicine has been authorised

It was demonstrated that Ponvory, with the active substance ponesimod, reduced the number of relapses and the number and size of lesions in the brain and spinal cord compared with treatment with teriflunomide. Based on all the available data, the benefits of Ponvory outweigh the risks.

The medicinal product Ponvory, with the active substance ponesimod, has been authorised in Switzerland for the treatment of adult patients with active, relapsing-remitting forms of multiple sclerosis (RRMS).

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Ponvory®

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

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

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