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Ponvory (*ponesimod*)

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

What is Ponvory and what is it used for?

Ponvory is a medicine for treating adults with relapsing active forms of multiple sclerosis.

Multiple sclerosis is a disease of the brain and spinal cord in which inflammation attacks the protective covering (sheath) around nerves and damages the nerves themselves.

Ponvory contains the active substance ponesimod.

How is Ponvory used?

Ponvory is available as tablets. For the first two weeks, the patient takes tablets once daily with the dose increasing from 2 mg to 10 mg. After two weeks the patient takes a single 20 mg tablet once a day.

The medicine can only be obtained with a prescription. Treatment is started under the supervision of a doctor experienced in managing multiple sclerosis. For more information, including about the dosing, see the package leaflet or contact your doctor or pharmacist.

How does Ponvory work?

In multiple sclerosis, the immune system (the body's natural defences) incorrectly attacks the protective sheath around the nerves and the nerves themselves in the brain and spinal cord.

The active substance in Ponvory, ponesimod, blocks T cells and B cells (two types of white blood cells involved in the immune system) inside the lymph nodes. Ponesimod does this by binding to a target (receptor), called the sphingosine-1-phosphate receptor, on the surface of T cells and B cells, which the cells need to leave the lymph nodes. By blocking these cells in the lymph nodes, Ponvory prevents them from traveling towards the brain and spinal cord, thus limiting the damage they cause in patients with multiple sclerosis.

What benefits of Ponvory have been shown in studies?

A main study involving 1,133 adults with relapsing forms of multiple sclerosis showed that Ponvory was more effective than another multiple sclerosis medicine, teriflunomide, at reducing the number of

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relapses (flare-ups). After two years of treatment, the average number of relapses a year in patients taking Ponvory was 0.2 compared with 0.3 in patients taking teriflunomide. The average number of relapses in a year was reduced by about a third in patients taking Ponvory compared with patients taking teriflunomide.

What are the risks associated with Ponvory?

The most common side effects of Ponvory (which may affect more than 1 in 10 people) are infections of the nose and throat and increased levels of liver enzymes. For the full list of side effects of Ponvory, see the package leaflet.

Ponvory must not be used in patients who have recently experienced certain heart problems or stroke and in patients with problems with heart rhythm, severely weakened immune system, severe or long-term infections, cancer, or moderate or severe liver problems. It must also not be taken during pregnancy or by women who can have children and are not using effective contraception. For the full list of restrictions, see the package leaflet.

Why is Ponvory authorised in the EU?

A main study showed that Ponvory was more effective than teriflunomide at reducing the number of relapses in patients with relapsing forms of multiple sclerosis. The side effects that occur with Ponvory are similar to those seen with medicines of the same class and are considered manageable.

The European Medicines Agency therefore decided that Ponvory's benefits are greater than its risks and that it can be authorised for use in the EU.

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

The company that markets Ponvory must distribute educational material for healthcare professionals and patients with information on the use of the medicine, such as dosing, monitoring and tests to be carried out before treatment. The company will also provide information about avoiding pregnancy while taking Ponvory.

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

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

Other information about Ponvory

Ponvory received a marketing authorisation valid throughout the EU on 19 May 2021.

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

This overview was last updated in 05-2021.