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EPAR summary for the public

Mavenclad

cladribine

This is a summary of the European public assessment report (EPAR) for Mavenclad. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Mavenclad.

For practical information about using Mavenclad, patients should read the package leaflet or contact their doctor or pharmacist.

What is Mavenclad and what is it used for?

Mavenclad is a medicine used to treat adults with the relapsing forms of multiple sclerosis, a disease in which inflammation damages the protective sheath around the nerve cells in the brain and spinal cord. Relapsing means that the patient has repeated flare-ups of the symptoms.

Mavenclad is used in patients whose disease is highly active. It contains the active substance cladribine.

How is Mavenclad used?

Mavenclad can only be obtained with a prescription and treatment must be started and supervised by a doctor experienced in treating multiple sclerosis.

The dose depends on patients' body weight and treatment consists of two courses spread over 2 years. The first year, patients take one to two tablets a day for 4 or 5 days; after one month, they again take one to two tablets a day for 4 or 5 days, adding up to a total dose of 1.75 mg per kg body weight over the two periods. This treatment course is repeated one year later. No other medicines should be taken within 3 hours of a Mavenclad tablet. For more information, see the package leaflet.

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How does Mavenclad work?

In multiple sclerosis, the body's immune (defence) system attacks and damages the protective sheath around the nerve cells in the central nervous system (the brain and spinal cord). The immune cells called lymphocytes play a key role in this process.

The active substance in Mavenclad, cladribine, has a similar chemical structure to purine, one of the substances needed to make up the DNA. In the body, cladribine is taken up by cells such as lymphocytes and interferes with the production of new DNA. This brings about the death of the lymphocytes, slowing down the progression of multiple sclerosis.

Cladribine is already approved in the EU for the treatment of certain leukaemias (cancers affecting lymphocytes).

What benefits of Mavenclad have been shown in studies?

Mavenclad has been shown to be effective in one main study involving 1,326 patients with relapsing-remitting multiple sclerosis. The study compared the effect of Mavenclad and placebo (a dummy treatment) in reducing the relapse rate 96 weeks after the start of treatment. Patients treated with Mavenclad had a relapse rate of 0.14 per year on average, compared with 0.33 for patients given placebo; at the end of 96 weeks, around 8 out 10 patients given standard doses of Mavenclad and 6 out of 10 given placebo had not had a relapse. In addition, patients given Mavenclad were nearly 50% less likely to have disease progression (indicated as an increase in disability that lasted for at least 6 months). The results suggested that the effects were greatest in patients with highly active disease and that benefit might be expected in other relapsing forms of multiple sclerosis. In a follow-up study for up to a further 2 years, benefit of the original treatment was maintained but there seemed no additional benefit from giving more than 2 courses of Mavenclad treatment.

What are the risks associated with Mavenclad?

The most common side effects with Mavenclad are lymphopenia (reduction in lymphocytes, which may affect more than 1 in 10 people) and infections with herpes zoster virus, in up to 1 patient in 10. Rashes, hair loss and lowered counts of another type of white blood cell, neutrophils, may also affect up to 1 patient in 10. For the full list of all side effects reported with Mavenclad, see the package leaflet.

Effects on lymphocytes reduce the body's immune defence against infections and cancer: Mavenclad must not be given to patients with active long-term infections such as tuberculosis or hepatitis, nor to patients with HIV infection or whose immune defences are weakened for other reasons such as treatment with medicines that suppress the immune system. It must not be given to patients with active cancers. Treatment must also be avoided in patients whose kidney function is moderately or severely reduced, and in women who are pregnant or breast feeding. For the full list of restrictions, see the package leaflet.

Why is Mavenclad approved?

Mavenclad has been shown to reduce relapse rates and delay disease progression in patients with relapsing multiple sclerosis. This appeared to be most marked in patients with highly active disease, in whom the clinical benefits were considered to outweigh the risks of a severe long-term lowering in lymphocyte numbers, which increases the risk of infection and possibly of cancer. In addition, the fact that Mavenclad is given by mouth, and requires only 2 short courses 12 months apart, offers an

advantage to patients. The European Medicines Agency therefore decided that Mavenclad's benefits are greater than its risks and recommended that it be approved for use in the EU.

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

The company that markets Mavenclad will provide information on the medicine for healthcare professionals and patients, including advice on the side effects and safety concerns, the need for monitoring before and during treatment, and on pregnancy prevention and effective contraception in both female and male patients.

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

Other information about Mavenclad

The European Commission granted a marketing authorisation valid throughout the European Union for Mavenclad on 22 August 2017.

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

This summary was last updated in 08-2017.