Generic Name:
Cladribine
Trade Name:
Mavenclad
Company:
EMD Serono
Notes:

FDA approved cladribine tablets to treat relapsing forms of multiple sclerosis (MS) in adults, to include relapsing-remitting disease and active secondary progressive disease.

Cladribine is not recommended for patients with MS who have clinically isolated syndrome. Because of its safety profile, its use is generally recommended for patients who have had an inadequate response to, or are unable to tolerate, an alternate drug indicated for treatment of MS.

The drug's efficacy was shown in a clinical trial in 1,326 patients with relapsing forms of MS who had least one relapse in the previous 12 months. Compared with placebo, cladribine significantly decreased the number of relapses and also reduced progression of disability.

Cladribine must be dispensed with a patient Medication Guide and has a boxed warning for an increased risk of malignancy and fetal harm. It should not to be used in patients with current malignancy. In patients with prior malignancy or with increased risk of malignancy, health professionals should evaluate its benefits and risks on an individual patient basis. They should also follow standard cancer screening guidelines in patients treated with cladribine.

The drug should not be used in pregnant women and in women and men of reproductive potential who do not plan to use effective contraception during treatment and for 6 months after drug therapy because of the potential for fetal harm. The drug must be stopped if the patient becomes pregnant.

Other warnings include the risk of decreased lymphocyte counts, hematologic toxicity, and bone marrow suppression. Health professionals should measure a patient?s complete blood counts and lymphocyte counts before, during, and after treatment. The drug may increase the risk of infections, so health professionals should screen patients for infections and delay treatment with cladribine if necessary.

The drug has been associated with graft-versus-host-disease following blood transfusions with nonirradiated blood. It may cause liver injury, and treatment should be interrupted or discontinued, as appropriate, if clinically significant liver injury is suspected.

The most common adverse reactions reported in the clinical trials included upper respiratory tract infections, headache, and decreased lymphocyte counts.

Medication Monitor Categories:
Supplemental Approvals