

MAVENCLAD Important Safety Information

What is MAVENCLAD?

MAVENCLAD is a prescription medicine used to treat relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, MAVENCLAD is generally used in people who have tried another MS medicine that they could not tolerate or that has not worked well enough.

MAVENCLAD is not recommended for use in people with clinically isolated syndrome (CIS).

It is not known if MAVENCLAD is safe and effective in children under 18 years of age and is therefore not recommended.

MAVENCLAD may cause serious side effects, including:

- **Risk of cancer (malignancies).** You should follow healthcare provider instructions about screening for cancer.
- **MAVENCLAD may cause birth defects if used during pregnancy. Females must not be pregnant when they start treatment with MAVENCLAD or become pregnant during MAVENCLAD dosing and within 6 months after the last dose of each yearly treatment course. You should stop treatment with MAVENCLAD and contact your healthcare provider right away if you become pregnant during treatment with MAVENCLAD.**
 - For females who are able to become pregnant:
 - Your healthcare provider should order a pregnancy test before you begin your first and second yearly treatment course of MAVENCLAD to make sure that you are not pregnant.
 - Use effective birth control (contraception) on the days on which you take MAVENCLAD and for at least 6 months after the last dose of each yearly treatment course.
 - Talk to your healthcare provider if you use oral contraceptives (the “pill”).
 - You should use a second method of birth control on the days on which you take MAVENCLAD and for at least 4 weeks after your last dose of each yearly treatment course.
 - For males with female partners who are able to become pregnant:
 - Use effective birth control (contraception) during the days on which you take MAVENCLAD and for at least 6 months after the last dose of each yearly treatment course.

Do not take MAVENCLAD if you:

- have cancer (malignancy).
- are pregnant, plan to become pregnant, or are a woman of childbearing age or a man able to father a child and you are not using birth control.
- are breastfeeding.
- are human immunodeficiency virus (HIV) positive.
- have active infections, including tuberculosis (TB), hepatitis B or C.
- are allergic to cladribine.

Before you take MAVENCLAD, tell your healthcare provider about all of your medical conditions, including if you:

- think you have an infection.
- have taken, take, or plan to take medicines that affect your immune system or blood cells, or other treatments for MS. Certain medicines can increase your risk of getting an infection.
- have had a recent vaccination or are scheduled to receive any vaccinations. You should not receive live or live-attenuated vaccines within the 4 to 6 weeks preceding treatment with MAVENCLAD or receive these types of vaccines during your treatment with MAVENCLAD and unless directed by your healthcare provider.
- have heart failure.
- have or have had cancer.
- have liver or kidney problems.
- are breastfeeding or plan to breastfeed. It is not known if MAVENCLAD passes into your breast milk. Do not breastfeed on the days on which you take MAVENCLAD, and for 10 days after the last dose.

How should I take MAVENCLAD?

- MAVENCLAD is given as two yearly treatment courses.
- Each yearly treatment course consists of 2 treatment weeks (also called cycles) that will be about a month apart.
- Take MAVENCLAD with water and swallow whole without chewing. MAVENCLAD can be taken with or without food.
- Swallow MAVENCLAD right away after opening the blister pack.

- Your hands must be dry when handling MAVENCLAD and washed well with water afterwards.
- Limit contact with your skin. Avoid touching your nose, eyes and other parts of the body. If you get MAVENCLAD on your skin or on any surface, wash it right away with water.
- Take MAVENCLAD at least 3 hours apart from other medicines taken by mouth during the 4- to 5-day MAVENCLAD treatment week.
- If you miss a dose, take it as soon as you remember on the same day. If the whole day passes before you remember, take your missed dose the next day. Do not take 2 doses at the same time. Instead, you will extend the number of days in that treatment week.

Your healthcare provider will continue to monitor your health during the 2 yearly treatment courses, and for at least another 2 years during which you do not need to take MAVENCLAD. It is not known if MAVENCLAD is safe and effective in people who restart MAVENCLAD treatment more than 2 years after completing 2 yearly treatment courses.

MAVENCLAD can cause serious side effects. If you have any of these symptoms listed below, call your healthcare provider right away:

- **low blood cell counts** have happened and can increase your risk of infections during treatment with MAVENCLAD. Blood tests are needed before you start treatment with MAVENCLAD, during your treatment with MAVENCLAD, and afterward, as needed.
- **serious infections such as:**
 - **TB, hepatitis B or C, and shingles (herpes zoster).** Fatal cases of TB and hepatitis have happened with cladribine during clinical studies. Tell your healthcare provider right away if you get any symptoms of the following infection related problems or if any of the symptoms get worse, including: fever, aching painful muscles, headache, feeling of being generally unwell, loss of appetite, burning, tingling, numbness or itchiness of the skin in the affected area, skin blotches, blistered rash, or severe pain.
 - **progressive multifocal leukoencephalopathy (PML).** PML is a rare brain infection that usually leads to death or severe disability. Although PML has not been seen in MS patients taking MAVENCLAD, it may happen in people with weakened immune systems. Tell your healthcare provider right away if you have any new or worsening neurologic signs or symptoms. These may include: weakness on 1 side of your body, loss of coordination in your arms and legs, decreased strength, problems with balance, changes in your vision, changes in your thinking or memory, confusion, or changes in your personality.
- **liver problems.** Blood tests should be performed to check your liver before you start taking MAVENCLAD. Symptoms of liver problems may include: nausea, vomiting, stomach pain, tiredness, loss of appetite, dark urine, or your skin or the whites of your eyes turn yellow.
- **allergic reactions (hypersensitivities).** You should stop treatment and seek immediate medical attention if any signs or symptoms of allergic reactions occur. Symptoms of an allergic reaction may include: skin rash, swelling or itching of the face, lips, tongue or throat, or trouble breathing.
- **heart failure.** MAVENCLAD may cause heart failure, which means your heart may not pump as well as it should. Call your healthcare provider or go to the closest emergency room for medical help right away if you have any signs or symptoms such as shortness of breath, a fast or irregular heart beat, or unusual swelling in your body.

The most common side effects of MAVENCLAD include: upper respiratory infection, headache, and low white blood cell counts.

These are not all the possible side effects of MAVENCLAD. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please see full Prescribing Information/Medication Guide, including **serious side effects**, for additional Important Safety Information.