

## Conversation Starter

# DISCUSSING MAVENCLAD WITH YOUR HEALTHCARE PROVIDER

**MAVENCLAD is the first and only short-course oral therapy for relapsing forms of multiple sclerosis.**

### **What is MAVENCLAD?**

MAVENCLAD is 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).

**MAVENCLAD may cause serious side effects.**

**Treatment with MAVENCLAD may increase your risk of developing cancer. You should follow healthcare provider instructions about screening for cancer. Because of the risk of fetal harm, do not take MAVENCLAD if you are pregnant or of childbearing potential and not using effective birth control.**

Please see additional Important Safety Information on pages 7-10 and MAVENCLAD **Prescribing Information** and **Medication Guide**, including **serious side effects**.



## Important Safety Information

**MAVENCLAD may cause serious side effects, including:**

- **Risk of cancer (malignancies).** Treatment with MAVENCLAD may increase your risk of developing cancer. 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.

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## Talk to your healthcare provider to see if MAVENCLAD is right for you

Choosing a treatment is an important decision for you and your healthcare provider. You have a lot to consider and explore.

Asking questions will help you get the information you need to make the right decision for you. You can **bring this guide with you to your healthcare provider's office** to help start a conversation about whether MAVENCLAD may be right for you.

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## THINKING ABOUT MAVENCLAD?

If you and your healthcare provider are considering MAVENCLAD as a treatment option, it's worth talking about:



### CLINICAL TRIAL RESULTS



### SHORT-COURSE ORAL DOSING



### SAFETY INFORMATION

#### Important Safety Information

**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; or are allergic to cladribine.

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## THINKING ABOUT MAVENCLAD?

Being ready with questions about MAVENCLAD ahead of time can help you get the most out of appointments with your healthcare provider. Here are some questions you may want to ask:

### MAVENCLAD EFFICACY (HOW WELL IT WORKS)

- Can MAVENCLAD be an effective treatment option for my relapsing MS?
- Has MAVENCLAD been shown to reduce the rate of relapses?
- Has MAVENCLAD been shown to slow the rate of disability progression?
- Has MAVENCLAD been shown to reduce the number of brain lesions?

### MAVENCLAD DOSING

- What can you tell me about MAVENCLAD dosing? How is it different from other MS treatments?

### MAVENCLAD SAFETY INFORMATION

- Once I start treatment, will I have to come back for any lab tests to monitor how I'm doing with MAVENCLAD?
- What side effects are associated with MAVENCLAD? Can you tell me about the risks I need to consider before treatment with MAVENCLAD?

### Important Safety Information

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

Please see additional Important Safety Information on pages 7–10 and MAVENCLAD **Prescribing Information** and **Medication Guide**, including **serious side effects**.

## TAKE ACTION

If you and your healthcare provider agree that MAVENCLAD is the right choice for you, make a plan to start.

Ask:

**When can I begin treatment with MAVENCLAD?**

**What's the process for starting?**

**What kind of follow-up appointments and tests should I expect?**

**Who can I speak to if I have questions or need support?**

**(If currently on medication) When will I need to stop taking my current medication?**

**MS**LifeLines®

### **WILL BE THERE TO SUPPORT YOU THROUGHOUT YOUR TREATMENT**

MS LifeLines is a patient support program sponsored by EMD Serono. It has been helping people with MS, and their care partners, for over 17 years.

MS LifeLines connects you with a team of over 100 Nurse Support Specialists, Field Nurse Educators, Financial Support Specialists, and Patient Support Specialists. They really understand what you go through. They've helped people in person and on over 4 million calls.

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## 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).** Treatment with MAVENCLAD may increase your risk of developing cancer. 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.

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Please see MAVENCLAD **Prescribing Information** and **Medication Guide**, including **serious side effects**.

- 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.

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- have heart failure.
- 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.

### **Additional information about taking MAVENCLAD**

- You should limit skin contact with the MAVENCLAD pills and wash hands and surfaces exposed to the pills.
- MAVENCLAD should be taken at least 3 hours apart from other medicines.

### **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).** Symptoms may include: 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 problems with thinking, balance, eyesight, weakness on 1 side of your body, strength, or using your arms or legs.
- **liver problems.** Blood tests should be performed to check your liver before you

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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.

**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.

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