

# I'M READY

For a relapsing MS treatment that's  
not an infusion, not an injection, not a daily pill.\*

\*Not taken every day of the year.

Maby  
MAVENCLAD patient since 2019



## 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.**

Please see additional Important Safety Information on pages 20-22 and click to view [MAVENCLAD Prescribing Information](#) and [Medication Guide](#), including **serious side effects**.

### This brochure will help you learn about MAVENCLAD® (cladribine) tablets 10 mg, including:

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#### Learn about MAVENCLAD

Attend an educational event hosted by a healthcare provider. You'll hear how MAVENCLAD is thought to work, learn about its convenient dosing schedule, and meet others with MS.

For more information about MAVENCLAD, and to find webinars and live events near you, go to **MavencladEvents.com** 

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**Real** results



**No more than 10 oral  
treatment days**  
a year for 2 years\*



**17+ years** of safety  
data from clinical trials,  
follow-up, and real-  
world experience in MS



Approved in **50+**  
countries worldwide,  
including the U.S.

\*Your healthcare provider will continue to monitor your health during the 2 yearly treatment courses, as well as between treatment courses and for at least another 2 years, during which you do not need to take MAVENCLAD. Your healthcare provider may delay or completely stop treatment with MAVENCLAD if you have severe side effects. It is not known if it is safe and effective for people to restart MAVENCLAD after the full 4-year period.

### **Important Safety Information (cont.)**

**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 breast-feeding; are human immunodeficiency virus (HIV) positive, have active infections, including tuberculosis (TB), hepatitis B or C, or are allergic to cladribine.

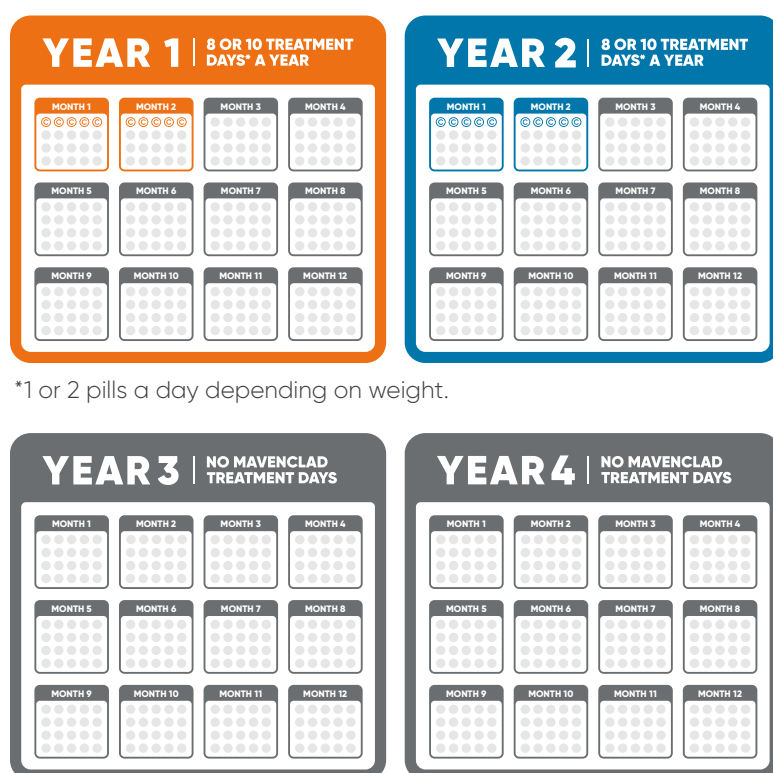
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## Convenient dosing

MAVENCLAD is the first and only short-course oral therapy with **no more than 10 treatment days a year for 2 years.**

**MAVENCLAD is taken over 2 weeks in the first year and over 2 weeks in the second year.**

For each week of treatment, you'll take 1 or 2 pills per day for up to 5 days, then about a month later, another 1 or 2 pills per day for up to 5 days. Then you don't have to take MAVENCLAD the rest of the year. The number of pills you take per day will depend on your weight.



\*1 or 2 pills a day depending on weight.

### What happens once you've taken MAVENCLAD

Your healthcare provider will continue to monitor your health during the 2 yearly treatment courses, as well as between treatment courses and for at least another 2 years, during which you do not need to take MAVENCLAD. Your healthcare provider may delay or completely stop treatment with MAVENCLAD if you have severe side effects, dosing schedule, and meet others with MS.


### Important Safety Information (cont.)

**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; 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.

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# MAVENCLAD and other MS treatments

These charts provide information about dosing only. They do not imply any product comparison regarding safety or efficacy.

 <b>Oral Treatment Options</b>		# of pills per year
<b>MAVENCLAD®</b> 1 or 2x per day for up to 10 days per year		<b>up to 20</b>
<b>Aubagio®</b> (teriflunomide) 1x per day		365
<b>Bafiertam™</b> (monomethyl fumarate) 2x per day		730
<b>Gilenya®</b> (fingolimod) 1x per day		365
<b>Mayzent®</b> (siponimod) 1x per day		365
<b>Ponvory™</b> (ponesimod) 1x per day		365
<b>Tecfidera®</b> (dimethyl fumarate) 2x per day		730
<b>Vumerity®</b> (diroximel fumarate) Up to 2 capsules, 2x per day		up to 1,446
<b>Zeposia®</b> (ozanimod) 1x per day		365

 <b>Injectable Treatment Options</b>		# of injections per year
<b>Avonex®</b> (interferon beta-1a) 1x per week		52
<b>Betaseron®/Extavia®</b> (interferon beta-1b) Every other day		182
<b>Copaxone®</b> (glatiramer acetate injection) 3x per week or 1x per day, depending on dose		156/365
<b>Kesimpta®</b> (ofatumumab) Initial dose 1x per week for 3 weeks, then 1x every month		12
<b>Plegridy®</b> (peginterferon beta-1a) 1x every 2 weeks		26
 <b>Infusion (IV) Treatment Options</b>		# of infusions per year
<b>Lemtrada®</b> (alemtuzumab) 5 consecutive days in 1 year		5
<b>Ocrevus®</b> (ocrelizumab) First dose is split and given as 2 separate IV infusions, every 6 months thereafter		2
<b>Tysabri®</b> (natalizumab) Every 28 days		13

This is not a complete list of all approved MS medications. For more information, talk to your healthcare provider. Registered trademarks are the property of their respective owners.

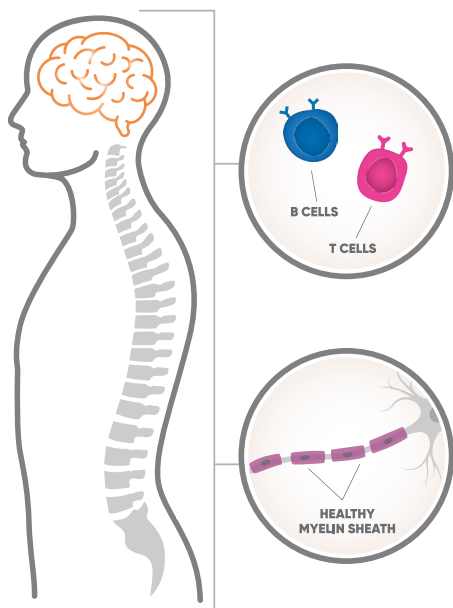
## Important Safety Information (cont.)

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).

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## Your immune system and MS



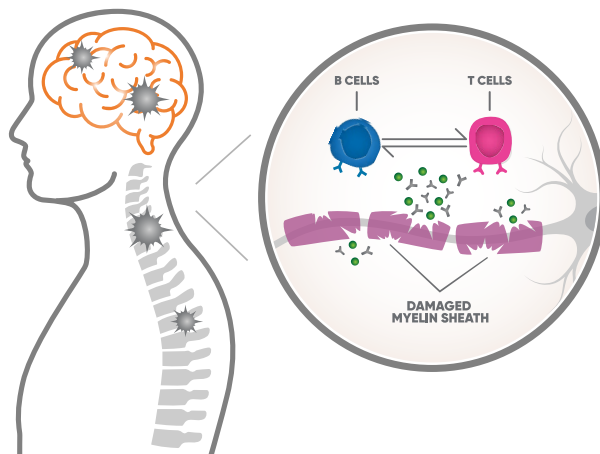
### Cells in your immune system work together to protect the body

Your immune system is made up of two different cell groups: innate immune cells, which are your body's first line of defense, and adaptive immune cells (including B and T cells), the second line of defense, which plays a role in your body's long-term immune response.

When your immune system is working properly, it defends your body against infection. When your immune system mistakenly attacks normal, healthy cells, it's considered an autoimmune condition, which is what multiple sclerosis is thought to be.

### In MS, the immune system mistakenly attacks the central nervous system, affecting the brain, spinal cord, and optic nerve

When you have MS, B and T cells recognize your normal, healthy tissues of the central nervous system as foreign. When this happens, the immune system (including B and T cells) attacks the myelin sheath, the insulating layer that protects nerve fibers in the central nervous system. The damage from these attacks causes inflammation and interrupts the signals between nerves, which shows up as lesions and MS-related symptoms.



*Graphics are for illustrative purposes only.*

### Important Safety Information (cont.)

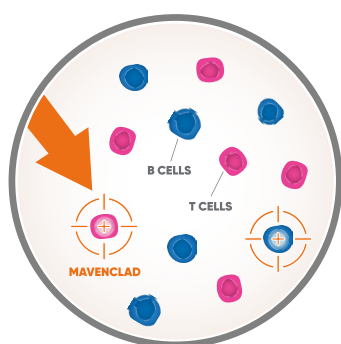
**Before you take MAVENCLAD, tell your healthcare provider about all of your medical conditions, including if you:** have taken, take, or plan to take medicines that affect your immune system or blood cells, or other treatments for MS.

Please see additional Important Safety Information on pages 20–22 and click to view [MAVENCLAD Prescribing Information](#) and [Medication Guide](#), including **serious side effects**.

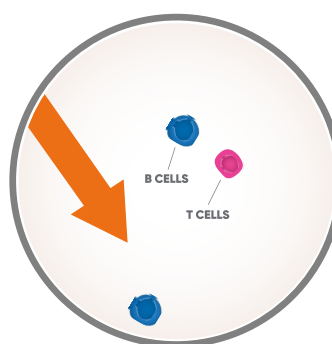
# Your immune system and MAVENCLAD

## MAVENCLAD targets and reduces the B and T cells that contribute to MS attacks

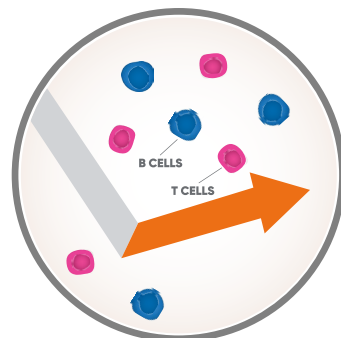
MAVENCLAD temporarily reduces the number of B and T cells circulating in the body. This means there are fewer such cells attacking the nerves of the central nervous system. Even when the body has a reduced number of these cells, other immune cells, including innate cells, are still present to defend the body from infection. However, MAVENCLAD can lower adaptive cell counts which may increase the likelihood of infections during treatment.



MAVENCLAD targets and reduces the B and T cells that contribute to MS attacks



Even when B and T cell counts are reduced, other immune cells are still present to defend the body from infections



## Over time, new B and T cells recover

MAVENCLAD is taken for up to 10 days each year for 2 years. After each treatment course and over several months, new B and T cell counts recover to near normal (although they may not go back to pre-treatment levels). Your healthcare provider will monitor your health and blood cell count and make adjustments if necessary.

*Graphics are for illustrative purposes only.*



MAVENCLAD will continue to treat your MS over the **2 treatment years—even when you're not actively taking it.**

## Important Safety Information (cont.)

Certain medicines can increase your risk of getting an infection; have had a recent vaccination or are scheduled to receive any vaccinations; 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.

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## How MAVENCLAD was studied

MAVENCLAD was studied in a 96-week clinical trial with relapsing MS patients to measure how well it works and to evaluate its safety.

**433** PEOPLE TOOK  
**MAVENCLAD**

92% completed the full 96 weeks of the study

**437** PEOPLE TOOK A  
**PLACEBO**

87% completed the full 96 weeks of the study

## See proven results of MAVENCLAD

Here's how MAVENCLAD performed when compared to placebo in a 96-week clinical study.

### Reduces the rate of relapses

**58%**  
**REDUCTION**  
**IN RELAPSE RATE**



MAVENCLAD reduced the rate of relapses per year by 58% (MAVENCLAD 0.14 vs placebo 0.33)

**81% WERE**  
**RELAPSE FREE**  
**AT THE END OF THE CLINICAL TRIAL**



Of patients taking MAVENCLAD, 81% were still free of relapses at 96 weeks vs 63% of patients not taking MAVENCLAD

### Important Safety Information (cont.)

**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 breast-feeding; are human immunodeficiency virus (HIV) positive, have active infections, including tuberculosis (TB), hepatitis B or C, or are allergic to cladribine.

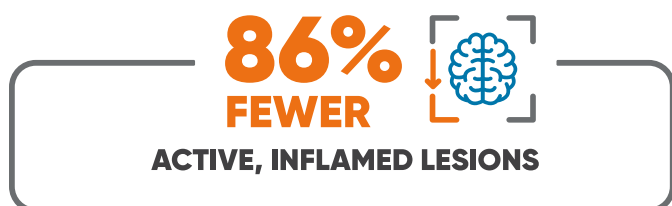
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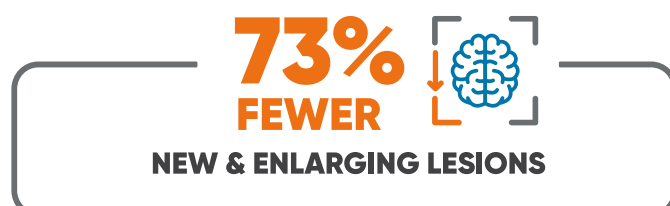
## Significantly decreases development of new and active lesions

**Patients taking MAVENCLAD had fewer lesions compared to patients not taking MAVENCLAD.**

The number of lesions can be seen through the 2 types of magnetic resonance imaging (MRI) scans typically used with MS.



Average number of T1-Gd+ lesions: MAVENCLAD 0.12 vs placebo 0.91. At 96 weeks, 13.2% (57 out of 433) of patients in the MAVENCLAD group had T1-Gd+ lesions vs 51.7% (226 out of 437) of patients in the placebo group. The mean relative reduction reflects that not all patients had lesions. Median number of lesions: MAVENCLAD 0 vs placebo 0.33.

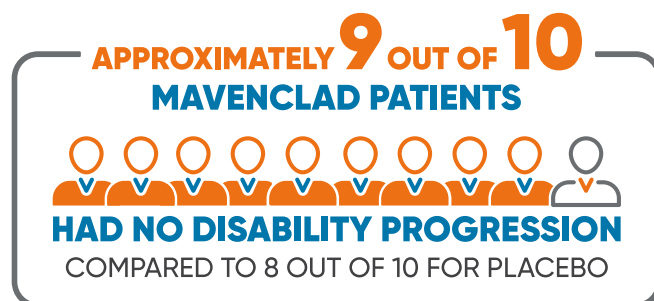


Average number of active T2 lesions: MAVENCLAD 0.38 vs placebo 1.43. At 96 weeks, 38.3% (166 out of 433) of patients in the MAVENCLAD group had active T2 lesions vs 71.6% (313 out of 437) of patients in the placebo group. The mean relative reduction reflects that not all patients had lesions. Median number of lesions: MAVENCLAD 0 vs placebo 0.67.

## Reduces disability progression\*



MAVENCLAD 13% vs placebo 19% with 3-month confirmed Expanded Disability Status Scale (EDSS) progression.



MAVENCLAD kept 87% of patients free from 3-month confirmed EDSS progression vs 81% on placebo.

\*Disability progression was defined as an increase of at least 1 point in the EDSS that was sustained for at least 3 months.

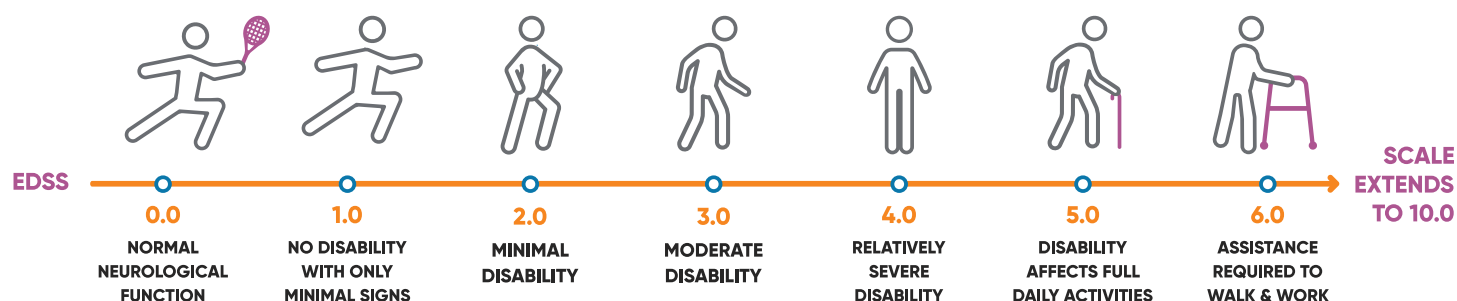
### Important Safety Information (cont.)

**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.

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## How is disability progression measured?

Disability progression is a common measure of MS treatments in clinical trials. It can be charted on the EDSS.



## NOTES

### Important Safety Information (cont.)

**How should I take MAVENCLAD? (cont.)** 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.

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## The safety profile of MAVENCLAD has been extensively evaluated

When it comes to choosing an MS treatment, safety is a key factor. That's why MAVENCLAD has been evaluated in clinical trials, follow-up, and real-world experience.



As part of the clinical trial program for MAVENCLAD, about 24% of cladribine-treated patients in the program were followed for up to 8 years. The average time of the study follow-up was about 4.8 years. This helped to provide a clearer picture of the long-term safety profile of MAVENCLAD.

It is not known if MAVENCLAD is safe and effective for people to restart MAVENCLAD treatment 2 years after completing their 2 yearly treatment courses.



**56,000+** people have been treated globally with MAVENCLAD in the real-world setting.

Please see additional Important Safety Information on pages 20-22 and click to view MAVENCLAD [Prescribing Information](#) and [Medication Guide](#), including **serious side effects**.

## Side effects

These clinical trials also evaluated the risk of side effects from MAVENCLAD. The types and seriousness of side effects vary from patient to patient. These are some of the possible, serious side effects with MAVENCLAD.



### Cancer (malignancies)

Treatment with MAVENCLAD may increase your risk of developing cancer. In clinical studies:

#### PATIENTS ON MAVENCLAD

**1.1%** DEVELOPED A  
MALIGNANCY

(10 OUT OF 923 PATIENTS)

VS

#### PATIENTS ON PLACEBO

**0.5%** DEVELOPED A  
MALIGNANCY

(3 OUT OF 641 PATIENTS)

Work with your healthcare team to determine which cancer screenings are necessary.



### Birth defects

Because of the risk of birth defects, do not take MAVENCLAD if you are pregnant or of childbearing potential and not using effective birth control. Patients should use effective birth control (contraception) while on treatment with MAVENCLAD and for at least 6 months after the last dose of each yearly treatment course.



### Low white blood cell count

Low blood cell counts have happened and may increase the risk of infections during treatment with MAVENCLAD. Your healthcare provider will do blood tests before, during, and after your treatment with MAVENCLAD, as needed.

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### Serious infections

Patients have experienced TB, hepatitis B or C, and shingles (herpes zoster). Fatal cases of TB (1 case) and hepatitis (1 case) have happened with cladribine during clinical studies. In clinical studies:

#### PATIENTS ON MAVENCLAD

**2%** DEVELOPED  
SHINGLES

(12 OUT OF 662 PATIENTS)\*

VS

#### PATIENTS ON PLACEBO

**0.2%** DEVELOPED  
SHINGLES

(1 OUT OF 641 PATIENTS)†

Talk to your healthcare provider to make sure your vaccinations are up to date.



### Progressive multifocal leukoencephalopathy (PML)

PML is a rare brain infection that usually leads to death or severe disability.

**No cases** of PML have been seen in MS patients taking MAVENCLAD, but it may happen in people with weakened immune systems.



### Liver problems

MAVENCLAD may cause liver problems. Your healthcare provider should do blood tests to check your liver before you start taking MAVENCLAD. In clinical studies:

#### PATIENTS ON MAVENCLAD

**0.3%** HAD LIVER  
PROBLEMS

(2 OUT OF 662 PATIENTS)

VS

#### PATIENTS ON PLACEBO

**0%** HAD LIVER  
PROBLEMS

(0 OUT OF 641 PATIENTS)

\*6% of MAVENCLAD-treated patients developed a herpes viral infection, of which 2% were herpes zoster and 2.6% were oral herpes.

†2% of placebo patients developed a herpes viral infection, of which 0.2% were herpes zoster and 1.2% were oral herpes.

Please see additional Important Safety Information on pages 20-22 and click to view MAVENCLAD [Prescribing Information](#) and [Medication Guide](#), including **serious side effects**.



### Allergic reactions (hypersensitivities)

MAVENCLAD can cause serious allergic reactions, such as skin rash, swelling or itching of the face, lips, tongue or throat, or trouble breathing. Stop your treatment with MAVENCLAD and go to the closest emergency room for help right away if you have any signs or symptoms of allergic reactions.



### 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 of heart failure. In clinical studies:

#### PATIENTS ON MAVENCLAD\*

**0.05%** HAD HEART FAILURE

(1 OUT OF 1,976 PATIENTS)

VS

#### PATIENTS ON PLACEBO

**0%** HAD HEART FAILURE

(0 OUT OF 802 PATIENTS)

\*Includes patients treated with both oral and IV forms of cladribine.

“



In addition to treatment, I try to maintain a good combination of mental and physical health, **creating good habits and doing things I enjoy.**

—Hossein, MAVENCLAD patient since 2019

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## Common side effects seen in clinical trials

Some of the most common side effects experienced by patients included:



### UPPER RESPIRATORY INFECTION

**PATIENTS ON  
MAVENCLAD** **38%**

**PATIENTS ON  
PLACEBO** **32%**



### HEADACHE

**PATIENTS ON  
MAVENCLAD** **25%**

**PATIENTS ON  
PLACEBO** **19%**



### LYMPHOPENIA (LOW WHITE BLOOD CELL COUNT)

**PATIENTS ON  
MAVENCLAD** **24%**

**PATIENTS ON  
PLACEBO** **2%**

The types and seriousness of side effects vary from patient to patient. For a list of possible side effects and their symptoms, please see the Medication Guide. This is not intended to replace discussions with your healthcare provider. If you think you are experiencing any of these side effects or symptoms, please talk to your healthcare provider immediately.

Call your doctor for medical advice about side effects. You may report side effects to FDA at **1-800-FDA-1088**.



### Get to know MAVENCLAD a bit better at the next in-person or virtual educational event.

Presentations are led by a healthcare provider who reviews how MAVENCLAD is thought to work, as well as its efficacy, safety profile, and dosing schedule.

To learn more and register for an event, visit **[MavencladEvents.com](https://MavencladEvents.com)**

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## Important considerations before getting started

If you and your healthcare provider are considering MAVENCLAD, there are a few important topics you may want to discuss before making decisions about your treatment journey.



### Tell your healthcare provider about all your medical conditions, including if you:

- think you have an infection, including tuberculosis (TB), hepatitis B or C, or HIV
- have heart failure
- have liver or kidney problems
- have taken, take, or plan to take medicines that affect your immune system or your blood cells, or other treatments for MS, cancer, ulcerative colitis, Crohn's disease, or psoriatic arthritis. Certain medicines can increase your risk of getting an infection
- have or have had cancer
- are pregnant, 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



### Blood tests

Before you begin treatment, your healthcare provider should perform some tests to rule out certain conditions and see if MAVENCLAD is right for you. A blood test is recommended:

- Before starting MAVENCLAD in years 1 and 2
- 2 and 6 months after your treatment in each year

Once you're prescribed treatment, your healthcare provider will continue to monitor you to see how you're doing. Your healthcare provider may delay or completely stop treatment with MAVENCLAD if you have severe side effects.



### Vaccinations

Before starting MAVENCLAD, tell your healthcare provider if you have had a recent vaccination or are scheduled to receive any vaccinations.

To learn what tests should be performed, check out the **Pre-treatment Checklist** by visiting [StartingMavenclad.com](https://StartingMavenclad.com)

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# Pregnancy precautions

Before you begin treatment with MAVENCLAD, there are certain precautions to take if you are of child-bearing age.



## For people taking MAVENCLAD, you should not:

- Be pregnant when you start MAVENCLAD
- Become pregnant during dosing
- Become pregnant within 6 months after the last dose in year 1 and year 2

Both men and women should use effective birth control while taking MAVENCLAD and for at least 6 months after the last dose in year 1 and year 2. Talk to your healthcare provider if you use birth control pills. You should use a second method of birth control on the days which you take MAVENCLAD and for at least 4 weeks after your last dose of each yearly treatment course.

Do not breastfeed on the days on which you take MAVENCLAD and for 10 days after each monthly dosing cycle. Stop treatment with MAVENCLAD and contact your healthcare provider right away if you become pregnant during treatment with MAVENCLAD.

## Use effective contraception during treatment and 6 months after the last dose in year 1 and year 2.

MONTH	1	2	3	4	5	6	7	8	9	10	11	12
YEAR 1	Ⓒ 4-5* DAYS†	Ⓒ 4-5* DAYS†										
USE EFFECTIVE CONTRACEPTION DURING TREATMENT AND 6 MONTHS AFTER THE LAST DOSE IN YEAR 1 AND YEAR 2.												
YEAR 2	Ⓒ 4-5* DAYS†	Ⓒ 4-5* DAYS†										

\*1 or 2 pills a day depending on weight.

†Treatment days.

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## MS support you can count on

MS LifeLines is a patient resource sponsored by EMD Serono that provides financial and treatment support through Financial Support Specialists and MS-certified nurses.

### Financial assistance for eligible patients

EMD Serono is committed to ensuring all eligible patients who have been prescribed MAVENCLAD have access to treatment.



**If you're eligible\* and have insurance, you may pay as little as \$0 co-pay or co-insurance for MAVENCLAD.**

MS LifeLines also offers other assistance programs, including free medication, to help eligible patients gain access to MAVENCLAD.

### MS LifeLines Financial Support Specialists can:



#### **Help verify insurance benefits**

to determine coverage and understand how much money you may have to pay for your medication (out-of-pocket expenses)



#### **Provide information**

about MS LifeLines financial assistance options and help determine if you qualify



**Work with specialty pharmacies** to facilitate treatment access and help coordinate treatment delivery

\*Some limitations are required by law. Patients covered by federal or state healthcare programs, including Medicare and Medicaid, are not eligible for assistance. This program is open to residents of the U.S. and Puerto Rico with relapsing forms of multiple sclerosis who are starting MAVENCLAD therapy or presently taking MAVENCLAD.

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## MS LifeLines Nurses are there for you

MS-certified nurses support you before, during, and in-between treatment by providing educational resources and information to help you understand and stay on track with MAVENCLAD.

### MS LifeLines Nurses can:



#### Help you get started on treatment

with an in-home visit, phone call, or video chat anytime during your two years of treatment



**Send you treatment reminders** by email or text if you need them



**Provide tips and MS education** to help manage certain symptoms



### Connect with MS LifeLines

Call us at **1-877-447-3243**

Monday through Friday • 8 AM to 8 PM ET / Saturday • 9 AM to 5 PM ET



“

My fight with MS is not done. But I'm not fighting alone. With support from my family, my neurologist, and **a treatment that works well for me, I'm determined to stay in the ring.**

-Ron, MAVENCLAD patient since 2019

Please see additional Important Safety Information on pages 20-22 and click to view MAVENCLAD [Prescribing Information](#) and [Medication Guide](#), including **serious side effects**.

## 7 IMPORTANT SAFETY INFORMATION

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### 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.

### 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.

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Please see additional Important Safety Information, and click to view MAVENCLAD [Prescribing Information](#) and [Medication Guide](#), including **serious side effects**.

## 7 IMPORTANT SAFETY INFORMATION (cont.)

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**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.

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## 7 IMPORTANT SAFETY INFORMATION (cont.)

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**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 additional Important Safety Information, and click to view MAVENCLAD **Prescribing Information** and **Medication Guide**, including **serious side effects**.

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# IT'S TIME

## TO ASK ABOUT MAVENCLAD.

Talk to your healthcare provider and ask if MAVENCLAD is right for you. **Visit MAVENCLAD.com** 



**Get talking points and helpful tips for talking with your doctor.**

Download the Doctor Discussion Guide at **TalkMavenclad.com** 



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