

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.

Abby
MAVENCLAD patient, dosed in 2021 and 2022



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.

IMPORTANT SAFETY INFORMATION

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. Women 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 [Important Safety Information](#) on pages 21-23.

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

1	MAVENCLAD Dosing	4-5
2	How MAVENCLAD May Work	6-7
3	Proven Efficacy	8-10
4	Safety & Side Effects	11-15
5	Starting Treatment	16-17
6	MS LifeLines [®]	18-19
7	Important Safety Information	20-22



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 

Please see [Important Safety Information](#) on pages 21-23.



Proven Efficacy



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



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



Approved in **90+**
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 breastfeeding; are human immunodeficiency virus (HIV) positive, have active infections, including tuberculosis (TB), hepatitis B or C, or are allergic to cladribine.

Please see [Important Safety Information](#) on pages 21-23.

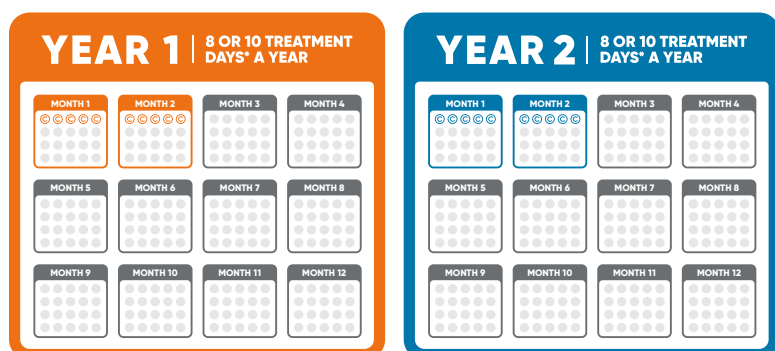
1 MAVENCLAD DOSING

Convenient dosing

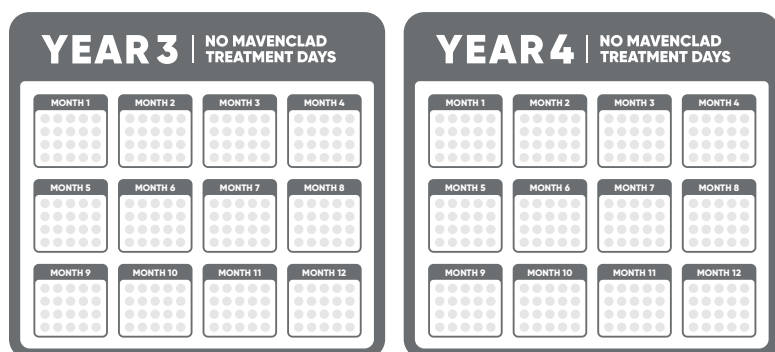
MAVENCLAD is the first and only short-course oral therapy with **no more than 10 treatment days a year for 2 years.**

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.

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.

Please see [Important Safety Information](#) on pages 21-23.

1 MAVENCLAD DOSING

MAVENCLAD and other MS treatments

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



Oral Treatment Options

of pills per year

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



Injectable Treatment Options

of injections per year

Avonex® (interferon beta-1a) 1x per week	52
Betaseron®/Extavia® (interferon beta-1b) Every other day	182
Copaxone® (glatiramer acetate injection) 3x per week or 1x per day, depending on dose	156/365
Kesimpta® (ofatumumab) Initial dose 1x per week for 3 weeks, then 1x every month	12
Plegridy® (peginterferon beta-1a) 1x every 2 weeks	26

Infusion (IV) Treatment Options	# of infusions per year
Briumvi® (ublituximab) 1-hour infusion	2
Lemtrada® (alemtuzumab) 5 consecutive days in 1 year	5
Ocrevus® (ocrelizumab) First dose is split and given as 2 separate IV infusions, every 6 months thereafter	2
Tysabri® (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.

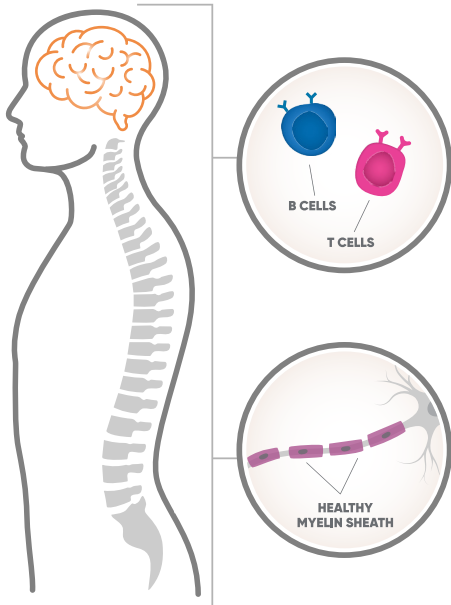
Important Safety Information (cont.)

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).

Please see [Important Safety Information](#) on pages 21-23.

Your immune system and MS



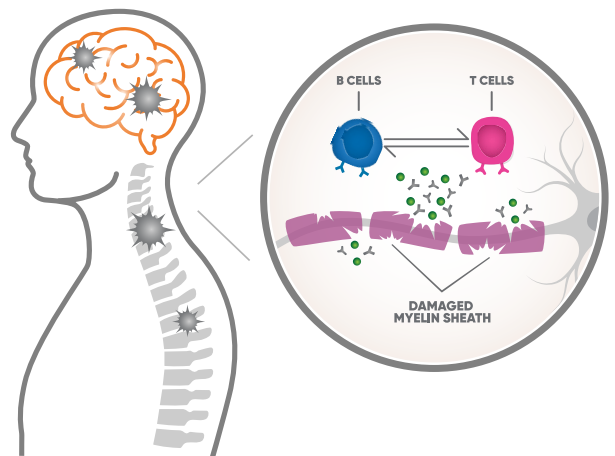
Cells in your immune system work together to protect the body

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.)

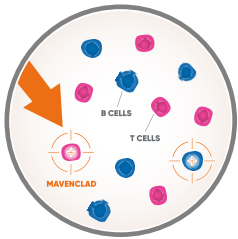
Before you take MAVENCLAD, tell your healthcare provider about all of your medical conditions, including if you: have taken, take, or plan to take medicines that affect your immune system or blood cells, or other treatments for MS. Certain medicines can increase your risk of getting an infection.

Please see [Important Safety Information](#) on pages 21-23.

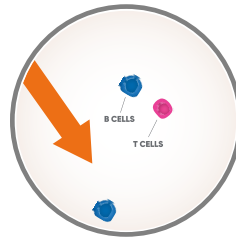
Your immune system and MAVENCLAD

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

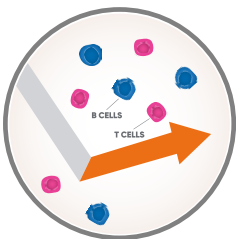
In MS, your immune system (including B and T cells) mistakenly attacks the central nervous system (CNS), affecting the brain, spinal cord, and optic nerve.



- MAVENCLAD temporarily reduces the number of B and T cells circulating in the body, so there are fewer such cells attacking the nerves of the CNS



- Even when the body has a reduced number of these cells, MAVENCLAD allows other immune cells to stay present to defend the body from infections and respond to vaccinations
- However, MAVENCLAD can lower white blood cell counts, which may increase the likelihood of infections during treatment



The short-course dosing of MAVENCLAD allows new B and T cells to recover over time.

Your immune system is only temporarily weakened.

- This is due to **non-continuous immunosuppression** and means your immune system may continue to fight infections and respond to vaccinations between and after each treatment course

The therapeutic effects of MAVENCLAD continue beyond dosing.

- The affected immune cells that trigger the mistaken attacks recover slowly over time, and newly repopulated cells may be less likely to cause inflammation associated with MS

Graphics are for illustrative purposes only.



MAVENCLAD will continue to treat your MS **even when you're not actively taking it.**

Important Safety Information (cont.)

Tell your healthcare provider if you 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.

Please see [Important Safety Information](#) on pages 21-23.

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
compared to **PLACEBO**



MAVENCLAD 0.14 vs placebo 0.33

81% OF MAVENCLAD
PATIENTS
were relapse free
compared to
63% **ON PLACEBO**
at the end of
the clinical trial



Important Safety Information (cont.)

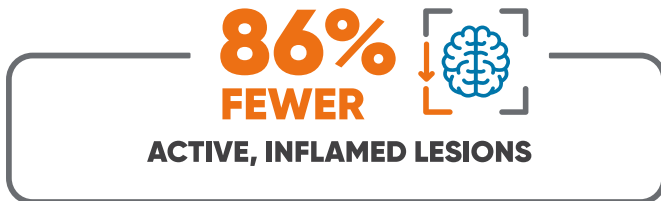
Do not take MAVENCLAD if you: have cancer (malignancy); are pregnant, plan to become pregnant, or are a woman of childbearing age or a man able to father a child and you are not using birth control; are breast-feeding; are human immunodeficiency virus (HIV) positive, have active infections, including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

Please see [Important Safety Information](#) on pages 21-23.

3 PROVEN EFFICACY

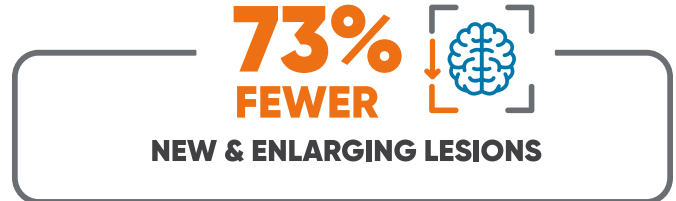
Significantly decreases development of new and active lesions

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.



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.

Reduces disability progression*

MAVENCLAD kept **87% of patients** free from 3-month confirmed Expanded Disability Status Scale (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.)

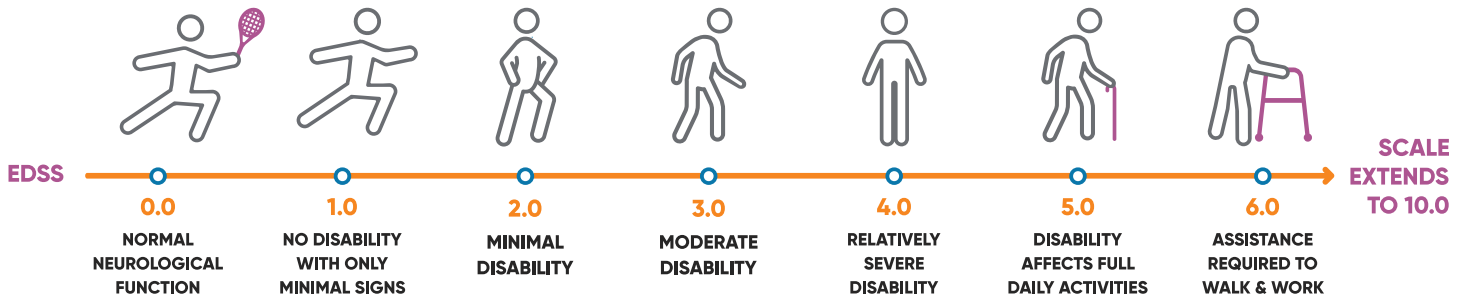
How should I take MAVENCLAD? MAVENCLAD is given as two yearly treatment courses, consisting of 2 treatment weeks (cycles) about a month apart. Handle MAVENCLAD with dry hands and take immediately after opening the blister pack. Take with water and do not chew the tablet. MAVENCLAD can be taken with or without food and should be taken at least 3 hours apart from other medicines. Wash your hands after handling MAVENCLAD. Limit contact with your skin (especially on your face). Wash skin and surfaces with water if contact occurs.

Please see [Important Safety Information](#) on pages 21-23.

3 PROVEN EFFICACY

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 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.

Please see [Important Safety Information](#) on pages 21-23.

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.



100,000+ people have been treated globally with MAVENCLAD in the real-world setting.

Please see [Important Safety Information](#) on pages 21-23.

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.

Please see [Important Safety Information](#) on pages 21-23.



Serious infections

Life-threatening or fatal infections caused by bacteria, viruses, parasites or fungi have been reported. Fatal cases of TB (1 case) and hepatitis (1 case) have happened with cladribine during clinical studies. In clinical studies:

PATIENTS ON MAVENCLAD

2.4% DEVELOPED
SERIOUS INFECTIONS
(16 OUT OF 662 PATIENTS)

VS

PATIENTS ON PLACEBO

2% DEVELOPED
SERIOUS INFECTIONS
(13 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)

Please see [Important Safety Information](#) on pages 21-23.

4 SAFETY & 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.

“



As a busy mom, I really appreciate that after taking my treatment five days a month, for two months, **I'm done with taking MAVENCLAD for the year.**

-Vickie, MAVENCLAD patient, dosed in 2019 and 2021

Please see [Important Safety Information](#) on pages 21-23.

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. To report SUSPECTED ADVERSE REACTIONS, contact EMD Serono at: **1-800-283-8088 ext. 5563** or FDA at **1-800-FDA-1088** or www.fda.gov/medwatch.



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

Please see [Important Safety Information](#) on pages 21-23.

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.
- 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.

Please see [Important Safety Information](#) on pages 21-23.

Screening and 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. Below are some of the recommended tests that may be performed before starting treatment with MAVENCLAD, and at various times throughout your treatment:



Cancer Screening



Pregnancy Test



Complete Blood Count (CBC):

- Before you start MAVENCLAD in Years 1 and 2
- 2 months and 6 months after you start treatment in each year



Magnetic Resonance Imaging (MRI)



Tests for infections such as:

- HIV
- Tuberculosis
- Hepatitis B and C



Immunizations and Vaccinations



Liver injury test:

- Before each treatment cycle in Years 1 and 2



To learn what tests should be performed, check out the **Pre-treatment Checklist** by visiting StartingMavenclad.com

Please see [Important Safety Information](#) on pages 21-23.

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 taking MAVENCLAD should use effective birth control while on treatment and for at least 6 months after the last dose in year 1 and year 2. Ask your healthcare provider which contraceptive method is right for you.

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 [†]										
YEAR 2	Ⓒ 4-5* DAYS [†]	Ⓒ 4-5* DAYS [†]										
YEAR 3												
YEAR 4												

*1 or 2 pills a day depending on weight.
[†]8 or 10 treatment days a year.

Please see [Important Safety Information](#) on pages 21-23.

MS support you can count on

MS LifeLines is a patient resource sponsored by EMD Serono that provides financial and treatment support through Patient 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 commercial insurance, you may pay as little as \$0 co-pay or co-insurance for MAVENCLAD.

\$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 Patient 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.

Please see [Important Safety Information](#) on pages 21-23.

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 with your treatment
during your two years on
MAVENCLAD



**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, dosed in 2019 and 2020

Please see [Important Safety Information](#) on pages 21-23.

7 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. Women 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 women 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.
 - Ask your healthcare provider which contraceptive method is right for you. Women and men being treated with MAVENCLAD should use effective birth control (contraception) on the days on which they 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.

Please see full [Prescribing Information](#) and [Medication Guide](#), including **serious side effects**.

7 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. 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, consisting of 2 treatment weeks (cycles) about a month apart.
- Handle MAVENCLAD with dry hands and take immediately after opening the blister pack. Take with water and do not chew the tablet. MAVENCLAD can be taken with or without food and should be taken at least 3 hours apart from other medicines.
- Wash your hands after handling MAVENCLAD. Limit contact with your skin (especially on your face). Wash skin and surfaces with water if contact occurs.
- 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.

Please see full [Prescribing Information](#) and [Medication Guide](#), including **serious side effects**.

7 IMPORTANT SAFETY INFORMATION (cont.)

- **serious infections such as:**
 - **life-threatening or fatal infections caused by bacteria, viruses, parasites or fungi.**
 - **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.** 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. Your doctor will perform blood tests to check your liver during treatment.
- **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 heartbeat, 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. To report SUSPECTED ADVERSE REACTIONS, contact EMD Serono at: **1-800-283-8088 ext. 5563** or FDA at **1-800-FDA-1088** or www.fda.gov/medwatch.

Please see full [Prescribing Information](#) and [Medication Guide](#), including **serious side effects**.

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



MAVENCLAD[®]
(cladribine) tablets 10 mg

Please see [Important Safety Information](#) on pages 21-23..



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