MAVENCLAD®
(cladribine) tablets 10 mg

GET READY TO PRESCRIBE YOUR PATIENTS MAVENCLAD

INDICATION

MAVENCLAD® (cladribine) tablets is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, use of MAVENCLAD is generally recommended for patients who have had an inadequate response to, or are unable to tolerate, an alternate drug indicated for the treatment of MS.

Limitations of Use: MAVENCLAD is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile.

IMPORTANT SAFETY INFORMATION

MAVENCLAD may increase the risk of malignancy. It is contraindicated in patients with current malignancy; evaluate the benefits and risks on an individual basis for patients with prior or increased risk of malignancy. It is contraindicated for use in pregnant women and in women and men of reproductive potential who do not plan to use effective contraception because of the risk of fetal harm.

Please see **Important Safety Information** on page 3 and the accompanying full **Prescribing Information**, including **boxed WARNING**, for additional information.

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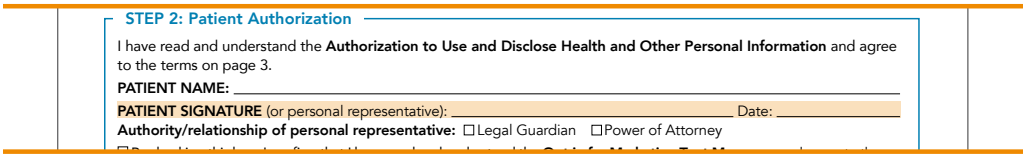
The MAVENCLAD Prescriptions and Service Request Form can be provided by your key Account Manager or downloaded on MavencladAccess.com where you can also access iAssist to submit electronically. If submitting by fax, please fax the required forms to 1-866-227-3243 and if you have any questions about the form, call MS LifeLines at 1-877-447-3243.

Best Practices when completing **the MAVENCLAD Prescription** and **Service Request Form**

1 Patient Authorization Information

- Patient confidentiality is very important to EMD Serono. Have your patient **read the Patient Authorization Information and sign the indicated area (2) on the Service Request Form**. The patient's signature will help to expedite your patient's enrollment in the MS LifeLines Patient Support program, which includes determining eligibility for MS LifeLines financial assistance programs.



STEP 2: Patient Authorization

I have read and understand the **Authorization to Use and Disclose Health and Other Personal Information** and agree to the terms on page 3.

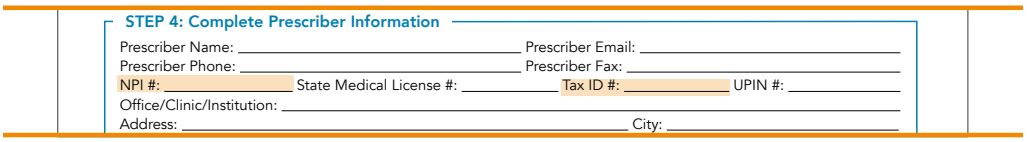
PATIENT NAME: _____

PATIENT SIGNATURE (or personal representative): _____ Date: _____

Authority/relationship of personal representative: ☐Legal Guardian ☐Power of Attorney

2 Complete prescriber information

- Ensure this information is complete to help expedite enrollment process
  - **NPI #** and **Tax ID #** are critical



STEP 4: Complete Prescriber Information

Prescriber Name: _____ Prescriber Email: _____

Prescriber Phone: _____ Prescriber Fax: _____

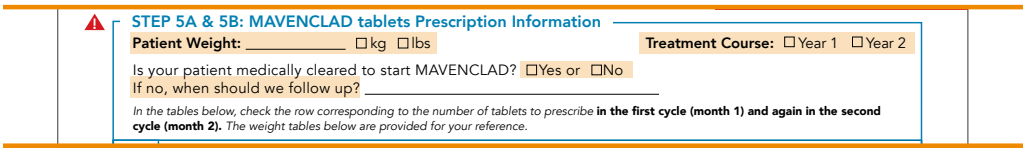
NPI #: _____ State Medical License #: _____ Tax ID #: _____ UPIN #: _____

Office/Clinic/Institution: _____

Address: _____ City: _____

3 Confirm Medical Clearance

- Enter patient weight and check **kilograms OR pounds**
- Indicate whether you are **prescribing year 1 or year 2 of treatment**. Please note, a separate SRF form is required for year 2
- **Check yes/no** as to whether your patient is medically cleared to start treatment (eg, has completed any pretreatment testing and assessments). **If your patient is not yet cleared to start**, fill in an approximate future start date.



STEP 5A & 5B: MAVENCLAD tablets Prescription Information

Patient Weight: _____ ☐kg ☐lbs **Treatment Course:** ☐Year 1 ☐Year 2

Is your patient medically cleared to start MAVENCLAD? ☐Yes or ☐No

If no, when should we follow up? _____

In the tables below, check the row corresponding to the number of tablets to prescribe **in the first cycle (month 1) and again in the second cycle (month 2).** *The weight tables below are provided for your reference.*

4 Complete prescription information

- Please note, you must **complete both 5A (Month 1) and 5B (Month 2) for this Treatment Year**. Failure to complete both 5A (Month 1) and 5B (Month 2) will require additional follow-up that may delay the prescription being filled for Month 2.
  - 5A. Check the row corresponding to the number of tablets to prescribe in the **first cycle (Month 1)** of this Treatment Year
  - 5B. Check the row corresponding to the number of tablets to prescribe in the **second cycle (Month 2)** of this Treatment Year

Prescriber must sign either "Dispense as written" OR "Substitution permitted" **for BOTH the First Cycle (Month 1) and the Second Cycle (Month 2) of this Treatment Year**.

5A FIRST CYCLE (Month 1): Number of MAVENCLAD 10-mg tablets per cycle

Weight Range: kg (~lb)	Day 1	Day 2	Day 3	Day 4	Day 5	Total # of Tablets Authorized in 1st Cycle (Month 1)
☐ 40 to <50 kg (88 to <110 lb)	1	1	1	1	0	4
☐ 50 to <60 kg (110 to <132 lb)	1	1	1	1	1	5
☐ 60 to <70 kg (132 to <154 lb)	2	1	1	1	1	6
☐ 70 to <80 kg (154 to <176 lb)	2	2	1	1	1	7
☐ 80 to <90 kg (176 to <198 lb)	2	2	2	1	1	8
☐ 90 to <100 kg (198 to <220 lb)	2	2	2	2	1	9
☐ 100 to <110 kg (220 to <242 lb)	2	2	2	2	2	10
☐ 110 kg and above (≥242 lb)	2	2	2	2	2	10

Please indicate DAW or substitution permitted by signing ONLY the applicable line.

Prescriber Signature (Dispense as written): _____ Date: _____

OR

Prescriber Signature (Substitution permitted): _____ Date: _____

Signature stamps not acceptable

No Refill. Instructions for Use: Take by mouth daily at intervals of 24 hours approximately the same time each day per product package instructions.

5B SECOND CYCLE (Month 2): Number of MAVENCLAD 10-mg tablets per cycle

Weight Range: kg (~lb)	Day 1	Day 2	Day 3	Day 4	Day 5	Total # of Tablets Authorized in 2nd Cycle (Month 2)
☐ 40 to <50 kg (88 to <110 lb)	1	1	1	1	0	4
☐ 50 to <60 kg (110 to <132 lb)	1	1	1	1	1	5
☐ 60 to <70 kg (132 to <154 lb)	2	1	1	1	1	6
☐ 70 to <80 kg (154 to <176 lb)	2	2	1	1	1	7
☐ 80 to <90 kg (176 to <198 lb)	2	2	1	1	1	7
☐ 90 to <100 kg (198 to <220 lb)	2	2	2	1	1	8
☐ 100 to <110 kg (220 to <242 lb)	2	2	2	2	1	9
☐ 110 kg and above (≥242 lb)	2	2	2	2	2	10

Please indicate DAW or substitution permitted by signing ONLY the applicable line.

Prescriber Signature (Dispense as written): _____ Date: _____

OR

Prescriber Signature (Substitution permitted): _____ Date: _____

No Refill. Instructions for Use: Take by mouth daily at intervals of 24 hours approximately the same time each day per product package instructions.

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Limitations of Use: MAVENCLAD is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile.

IMPORTANT SAFETY INFORMATION

WARNING: MALIGNANCIES and RISK OF TERATOGENICITY

- **Treatment with MAVENCLAD may increase the risk of malignancy. MAVENCLAD is contraindicated in patients with current malignancy. In patients with prior malignancy or with increased risk of malignancy, evaluate the benefits and risks of the use of MAVENCLAD on an individual patient basis. Follow standard cancer screening guidelines in patients treated with MAVENCLAD**
- **MAVENCLAD is contraindicated for use in pregnant women and in women and men of reproductive potential who do not plan to use effective contraception because of the potential for fetal harm. Malformations and embryolethality occurred in animals. Exclude pregnancy before the start of treatment with MAVENCLAD in females of reproductive potential. Advise females and males of reproductive potential to use effective contraception during MAVENCLAD dosing and for 6 months after the last dose in each treatment course. Stop MAVENCLAD if the patient becomes pregnant**

CONTRAINDICATIONS

- Patients with current malignancy.
- Pregnant women, and women and men of reproductive potential who do not plan to use effective contraception during and for 6 months after the last dose in each treatment course. May cause fetal harm.
- Patients with human immunodeficiency virus (HIV).
- Patients with active chronic infections (e.g., hepatitis or tuberculosis).
- Patients with a history of hypersensitivity to cladribine.
- Women intending to breastfeed while taking MAVENCLAD tablets and for 10 days after the last dose.

WARNINGS AND PRECAUTIONS

- **Malignancies:** Treatment with MAVENCLAD may increase the risk of malignancy. After the completion of 2 treatment courses, do not administer additional MAVENCLAD treatment during the next 2 years. The risk of malignancy with reinitiating MAVENCLAD more than 2 years after the completion of 2 treatment courses has not been studied. Follow standard cancer screening guidelines in patients treated with MAVENCLAD.
- **Risk of Teratogenicity:** MAVENCLAD may cause fetal harm when administered to pregnant women. In females of reproductive potential, exclude pregnancy before initiation of each treatment course of MAVENCLAD and prevent by the use of effective contraception during MAVENCLAD dosing and for at least 6 months after the last dose of each treatment course. Women who become pregnant during treatment with MAVENCLAD should discontinue treatment.
- **Lymphopenia:** MAVENCLAD causes a dose-dependent reduction in lymphocyte count. In clinical studies, 87% of MAVENCLAD-treated patients experienced lymphopenia. The lowest absolute lymphocyte counts occurred approximately 2 to 3 months after the start of each treatment course and were lower with each additional treatment course. Concomitant use of MAVENCLAD with hematotoxic drugs may increase the risk of adverse reactions because of the additive hematological effects. Monitor lymphocyte counts before and during treatment, periodically thereafter, and when clinically indicated.
- **Infections:** MAVENCLAD can reduce the body's immune defense and may increase the likelihood of infections. Infections occurred in 49% of MAVENCLAD-treated patients compared to 44% of patients treated with placebo in clinical studies. The most frequent serious infections included herpes zoster and pyelonephritis. Single fatal cases of tuberculosis and fulminant hepatitis B were reported in the clinical program. Administer live-attenuated or live vaccines at least 4 to 6 weeks prior to starting MAVENCLAD. Screen patients for latent infections; consider delaying treatment until infection is fully controlled. Vaccinate patients antibody-negative to varicella zoster virus prior to treatment. Administer anti-herpes prophylaxis in patients with lymphocyte counts less than 200 cells per microliter. Monitor for infections. In patients treated with parenteral cladribine for oncologic indications, cases of progressive multifocal leukoencephalopathy (PML) have been reported. No case of PML has been reported in clinical studies of cladribine in patients with MS.
- **Hematologic Toxicity:** In addition to lymphopenia, decreases in other blood cells and hematological parameters have been reported with MAVENCLAD in clinical studies. In general, mild to moderate decreases in neutrophil counts, hemoglobin levels, and platelet counts were observed. Severe decreases in neutrophil counts were observed in 3.6% of MAVENCLAD-treated patients, compared to 2.8% of placebo patients. Obtain complete blood count (CBC) with differential including lymphocyte count before and during treatment, periodically thereafter, and when clinically indicated.
- **Risk of Graft-versus-Host Disease With Blood Transfusions:** Transfusion-associated graft-versus-host disease has been observed rarely after transfusion of nonirradiated blood in patients treated with cladribine for non-MS treatment indications.
- **Liver Injury:** In clinical studies, 0.3% of MAVENCLAD-treated patients had liver injury (serious or causing treatment discontinuation) compared to 0 placebo patients. Obtain serum aminotransferase, alkaline phosphatase, and total bilirubin levels prior to treatment. Discontinue if clinically significant injury is suspected.
- **Hypersensitivity:** In clinical studies, 11% of MAVENCLAD-treated patients had hypersensitivity reactions, compared to 7% of placebo patients. Hypersensitivity reactions that were serious and/or led to discontinuation of MAVENCLAD, occurred in 0.5% of MAVENCLAD-treated patients, compared to 0.1% of placebo patients. If a hypersensitivity reaction is suspected, discontinue MAVENCLAD therapy. Do not use MAVENCLAD in patients with a history of hypersensitivity to cladribine.
- **Cardiac Failure:** In clinical studies, one MAVENCLAD-treated patient experienced life-threatening acute cardiac failure with myocarditis, which improved after approximately one week. Cases of cardiac failure have also been reported with parenteral cladribine used for treatment indications other than multiple sclerosis.

Adverse Reactions: The most common adverse reactions with an incidence of >20% for MAVENCLAD are upper respiratory tract infection, headache, and lymphopenia.

Drug Interactions/Concomitant Medication: Concomitant use of MAVENCLAD with immunosuppressive or myelosuppressive drugs and some immunomodulatory drugs (e.g., interferon beta) is not recommended and may increase the risk of adverse reactions. Acute short-term therapy with corticosteroids can be administered.

Avoid concomitant use of certain antiviral and antiretroviral drugs. Avoid concomitant use of BCRP or ENT/CNT inhibitors as they may alter bioavailability of MAVENCLAD.

Use in Specific Populations: Studies have not been performed in pediatric or elderly patients, pregnant or breastfeeding women. Use in patients with moderate to severe renal or hepatic impairment is not recommended.

Please see the accompanying full **Prescribing Information**, including **boxed WARNING**, for additional information.

EMD SERONO

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