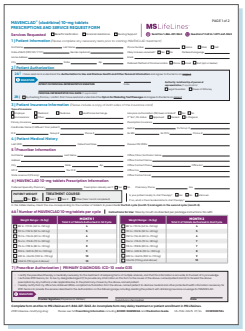
MAVENCLAD®
(cladribine) tablets 10 mg

Getting patients started with MAVENCLAD

Instructions for completing the MAVENCLAD Service Request Form (SRF)



DOWNLOAD THE SRF

INDICATION and IMPORTANT SAFETY INFORMATION for MAVENCLAD® (cladribine) tablets

MAVENCLAD® (cladribine) 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.

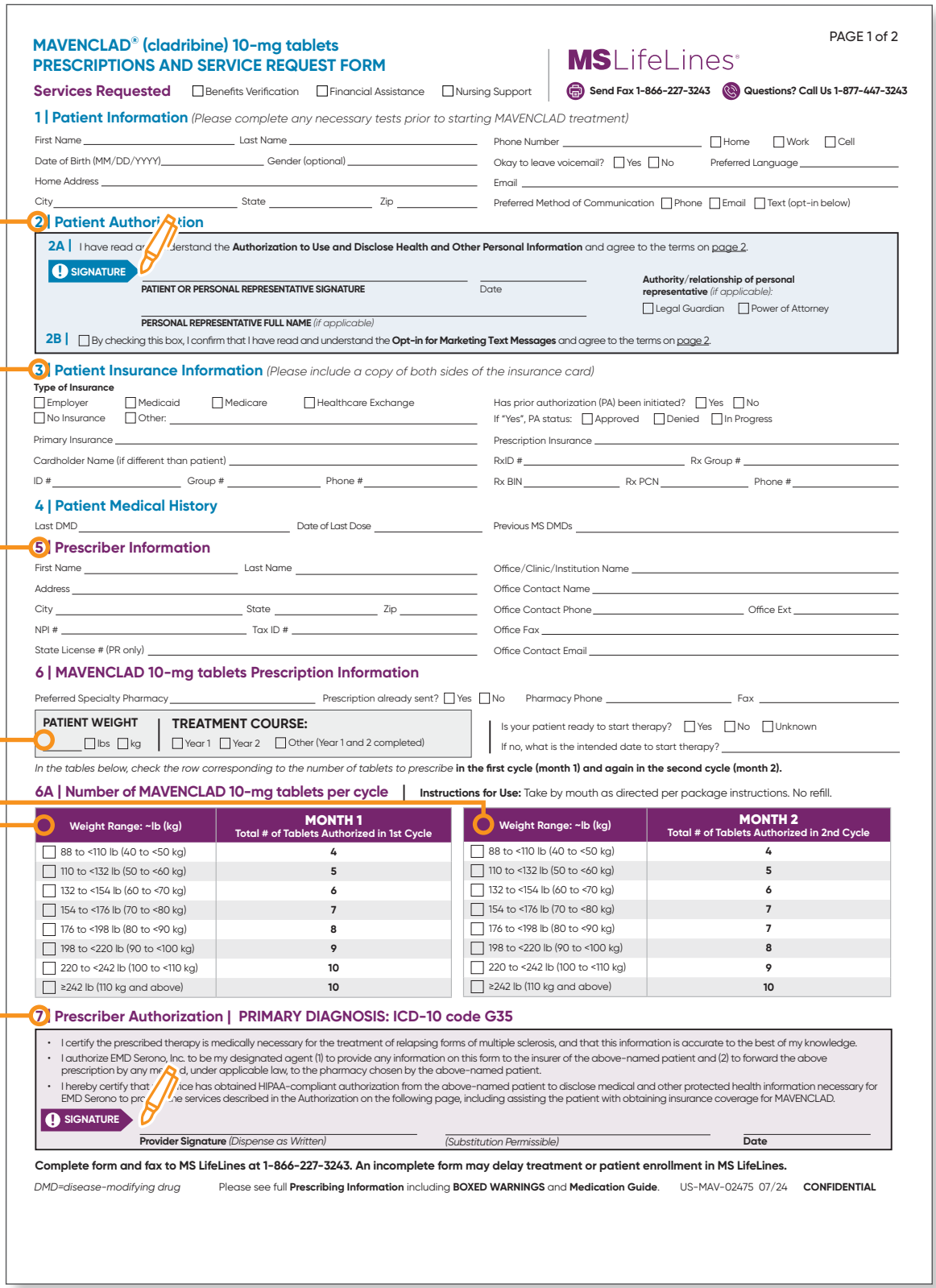
SELECT WARNING INFORMATION - MALIGNANCIES and TERATOGENICITY

MAVENCLAD may increase the risk of malignancy. MAVENCLAD 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. 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 risk of fetal harm.

Please see Important Safety Information including full **BOXED WARNINGS** on back cover and full Prescribing Information, for additional information.

DOWNLOAD THE SRF

SRF PAGE 1 INSTRUCTIONS



PAGE 1 of 2

MAVENCLAD® (cladribine) 10-mg tablets
PRESCRIPTIONS AND SERVICE REQUEST FORM

MSLifeLines®

Services Requested ☐ Benefits Verification ☐ Financial Assistance ☐ Nursing Support

Send Fax 1-866-227-3243 **Questions? Call Us 1-877-447-3243**

1 | Patient Information *(Please complete any necessary tests prior to starting MAVENCLAD treatment)*

First Name _____ Last Name _____ Phone Number _____ ☐ Home ☐ Work ☐ Cell

Date of Birth (MM/DD/YYYY)_____ Gender (optional) _____ Okay to leave voicemail? ☐ Yes ☐ No Preferred Language _____

Home Address _____ Email _____

City _____ State _____ Zip _____ Preferred Method of Communication ☐ Phone ☐ Email ☐ Text (opt-in below)

2 | Patient Authorization

2A | I have read and understand the **Authorization to Use and Disclose Health and Other Personal Information** and agree to the terms on page 2.

SIGNATURE _____ _____

PATIENT OR PERSONAL REPRESENTATIVE SIGNATURE Date

Authority/relationship of personal representative *(if applicable)*: ☐ Legal Guardian ☐ Power of Attorney

PERSONAL REPRESENTATIVE FULL NAME *(if applicable)*

2B | ☐ By checking this box, I confirm that I have read and understand the **Opt-in for Marketing Text Messages** and agree to the terms on page 2.

3 | Patient Insurance Information *(Please include a copy of both sides of the insurance card)*

Type of Insurance

☐ Employer ☐ Medicaid ☐ Medicare ☐ Healthcare Exchange ☐ No Insurance ☐ Other: _____

Has prior authorization (PA) been initiated? ☐ Yes ☐ No

If "Yes", PA status: ☐ Approved ☐ Denied ☐ In Progress

Primary Insurance _____ Prescription Insurance _____

Cardholder Name (if different than patient) _____ RxID # _____ Rx Group # _____

ID # _____ Group # _____ Phone # _____ Rx BIN _____ Rx PCN _____ Phone # _____

4 | Patient Medical History

Last DMD _____ Date of Last Dose _____ Previous MS DMDs _____

5 | Prescriber Information

First Name _____ Last Name _____ Office/Clinic/Institution Name _____

Address _____ Office Contact Name _____

City _____ State _____ Zip _____ Office Contact Phone _____ Office Ext _____

NPI # _____ Tax ID # _____ Office Fax _____

State License # (PR only) _____ Office Contact Email _____

6 | MAVENCLAD 10-mg tablets Prescription Information

Preferred Specialty Pharmacy _____ Prescription already sent? ☐ Yes ☐ No Pharmacy Phone _____ Fax _____

PATIENT WEIGHT _____ ☐ lbs ☐ kg | **TREATMENT COURSE:** ☐ Year 1 ☐ Year 2 ☐ Other (Year 1 and 2 completed)

Is your patient ready to start therapy? ☐ Yes ☐ No ☐ Unknown

If no, what is the intended date to start therapy? _____

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).**

6A | Number of MAVENCLAD 10-mg tablets per cycle | **Instructions for Use:** Take by mouth as directed per package instructions. No refill.

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

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

7 | Prescriber Authorization | PRIMARY DIAGNOSIS: ICD-10 code G35

- I certify the prescribed therapy is medically necessary for the treatment of relapsing forms of multiple sclerosis, and that this information is accurate to the best of my knowledge.
- I authorize EMD Serono, Inc. to be my designated agent (1) to provide any information on this form to the insurer of the above-named patient and (2) to forward the above prescription by any me[illegible]d, under applicable law, to the pharmacy chosen by the above-named patient.
- I hereby certify that [illegible]ice has obtained HIPAA-compliant authorization from the above-named patient to disclose medical and other protected health information necessary for EMD Serono to pro[illegible]e services described in the Authorization on the following page, including assisting the patient with obtaining insurance coverage for MAVENCLAD.

SIGNATURE _____ _____ _____

Provider Signature *(Dispense as Written)* *(Substitution Permissible)* **Date**

Complete form and fax to MS LifeLines at 1-866-227-3243. An incomplete form may delay treatment or patient enrollment in MS LifeLines.

DMD=disease-modifying drug Please see full **Prescribing Information** including **BOXED WARNINGS** and **Medication Guide**. US-MAV-02475 07/24 **CONFIDENTIAL**

Obtain patient signature.

Include all insurance information, including ID # and Group #.

Include all prescriber information, including NPI #.

Enter the patient's weight and indicate treatment course.

Complete both Month 1 and Month 2 for this Treatment Year:

- **Check the row** corresponding to the number of tablets to prescribe in each cycle.

Complete with Prescriber signature.

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SRF PAGE 2 INSTRUCTIONS

This page of the SRF describes the terms of the patient's authorization to use and disclose health and other personal information. It also describes that a patient can opt in to automated marketing text messages.

EMD SERONO

MSLifeLines®

Authorization to Use and Disclose Health and Other Personal Information

I authorize my treating physician(s), pharmacy(ies), health insurance company(ies), prescription drug plan(s), and other parties providing me health care or paying for my health care (collectively, "My Health Care Providers and Plans") to disclose my personal and protected health information ("Health Information") to EMD Serono, Inc. and its agents and representatives (collectively "EMD Serono"). My Health Information may include, but is not limited to, information regarding my diagnosis of and treatment for multiple sclerosis ("MS"), information included in a Prescription and Service Request Form, and any other information deemed relevant by My Health Care Providers and Plans that may be considered sensitive or specially protected by law. EMD Serono may use and further disclose my Health Information to My Health Care Providers and Plans or other third parties in order to: (1) enroll me in and administer the MS LifeLines Support Program and contact me by mail, email, or by live call at the telephone number(s) listed below, or to any future telephone number(s) provided by me; (2) conduct a benefits investigation and coordinate my insurance coverage for any prescribed EMD Serono product(s); (3) facilitate the filling of my prescription for and the delivery and administration of that product(s); (4) contact me regarding the MS LifeLines Support Program and conduct quality assurance, surveys, and other internal business activities in connection with the MS LifeLines Support Program; and (5) conduct marketing activities that includes, but is not limited to, providing me with educational and promotional materials, information, special offers, and services related to my therapy or my medical condition and/or to conduct market research activities that includes contacting me to participate in focus groups, surveys, or interviews that may be funded or sent by EMD Serono, a MS LifeLines Support Program, or an EMD Serono affiliate.

I understand that once my information is disclosed pursuant to this authorization, it may no longer be protected by federal privacy laws (eg, the Health Insurance Portability and Accountability Act [HIPAA]) or state privacy laws and may be further disclosed to others. However, I understand that EMD Serono will not release my personally identifiable information to any party, except as provided in this authorization or as permitted by applicable law, without first obtaining my (or my authorized representative's) separate written consent.

For more information on your privacy rights and choices, please see EMD Serono's privacy notice at https://www.emdserono.com/us-en/privacy-policy.html.

I understand that I may refuse to sign this authorization and such refusal will not affect my ability to receive any EMD Serono product, my treatment, payment for treatment, eligibility for or enrollment in health benefits, but it will limit my ability to receive MS LifeLines Support Program services. I understand that this authorization will remain in effect for 10 years, or such shorter period as may be required by state law, from the date of my signature unless I revoke it earlier by contacting EMD Serono in writing at EMD Serono & MS LifeLines, 200 Pier 4 Boulevard. Boston, MA 02210. If I revoke this authorization, My Health Care Providers and Plans will stop disclosing this information to EMD Serono, and EMD Serono will stop using and disclosing my information, as soon as possible, but the revocation will not affect prior use or disclosure of my information in reliance on this authorization.

I understand that certain of My Health Care Providers and Plans may receive compensation in exchange for their disclosure of my information to EMD Serono. I also understand that I have the right to receive a signed copy of this authorization.

To authorize your consent, please complete Step 2: Patient Authorization on page 1, including signature line.

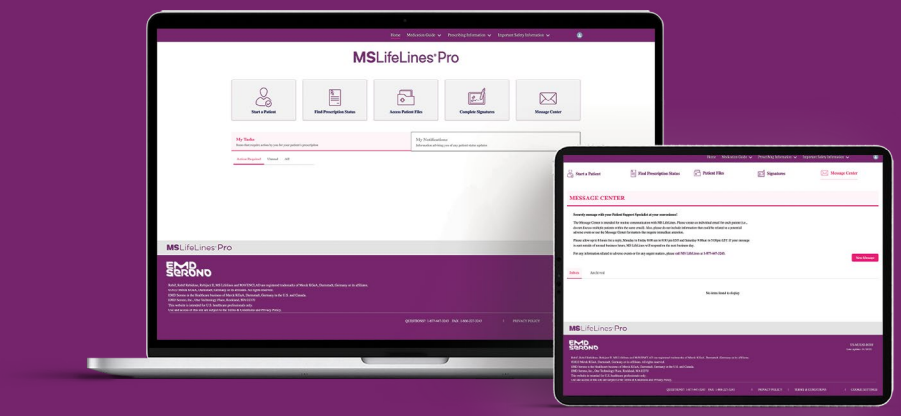
Opt-In for Automated Marketing Text Messages

I authorize EMD Serono, Inc. (or its agents), to send marketing text messages to the cell phone number(s) listed (or to any future telephone number(s) provided by me to EMD Serono, Inc. or its agents) using an automatic telephone dialing system on a recurring basis. This consent also enables EMD Serono to contact me by text message to provide me with MS LifeLines Support Program services. Signing this consent is not a condition of participating in the MS LifeLines Support Program or purchasing products, goods, or services from EMD Serono. I understand that my mobile phone service provider may charge me fees for texts sent to me, and I agree that EMD Serono will have no liability for the cost of any such calls or texts. At any time, I may withdraw my consent to receive text messages by replying "STOP" via return text message or contacting EMD Serono in writing at EMD Serono & MS LifeLines, 200 Pier 4 Boulevard. Boston, MA 02210.

To authorize your consent, please check the box listed in Step 2: Patient Authorization on page 1.

MS LifeLines is an educational support service for people living with MS and their families, and is sponsored by EMD Serono, Inc.

Prefer to prescribe online?



You can also prescribe MAVENCLAD online via the MS LifeLines Pro™ Portal

There you can:

- Electronically submit and sign prescriptions for MAVENCLAD
- View real-time patient journey status
- Take action on outstanding tasks or next steps
- Invite other office staff and prescribers to help manage patients on your behalf
- Send messages to the MS LifeLines team

LEAVE PAPERWORK BEHIND—VISIT MSLIFELINESPRO.COM

INDICATION and IMPORTANT SAFETY INFORMATION for MAVENCLAD® (cladribine) tablets

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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 infected 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 on a MAVENCLAD treatment day 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. In clinical studies, patients who received additional MAVENCLAD treatment within 2 years after the first 2 treatment courses had an increased incidence of malignancy. 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. Concomitant use of MAVENCLAD with hematotoxic drugs may increase the risk of adverse reactions because of the additive hematological effects. Monitor lymphocyte counts before, during, and after treatment.
- **Infections:** including life-threatening or fatal, infections have occurred. MAVENCLAD reduces the body's immune defense, and an increased risk of infections has been observed in patients receiving MAVENCLAD. Infections occurred in 49% of MAVENCLAD-treated patients compared to 44% of patients treated with placebo in clinical studies; serious or severe infections occurred in 2.4% of MAVENCLAD-treated patients and 2.0% of placebo-treated patients. The most frequent serious infections included herpes zoster and pyelonephritis. Fungal infections were observed, including cases of coccidioidomycosis. Single fatal cases of tuberculosis and fulminant hepatitis B were reported in the clinical program.
  - Screen patients for active and latent infections (tuberculosis, hepatitis B or C). Delay treatment until infection is fully resolved or controlled.
  - Vaccinate patients who are seronegative for varicella zoster virus (VZV) prior to treatment. Vaccinate patients who are seropositive to VZV with recombinant, adjuvanted zoster vaccine either prior to or during treatment, including when their lymphocyte counts are less than or equal to 500 cells per microliter.
  - Administer anti-herpes prophylaxis in patients with lymphocyte counts less than 200 cells per microliter. Monitor for infections.
  - Progressive multifocal leukoencephalopathy (PML) has been reported in patients treated with parenteral cladribine for oncologic indications. No case of PML has been reported in clinical studies of cladribine in patients with MS. Obtain a baseline magnetic resonance imaging (MRI) within 3 months before initiating the first treatment course of MAVENCLAD. At the first sign of PML, withhold MAVENCLAD and perform an evaluation.
  - Administer all immunizations (except as noted for VZV) according to immunization guidelines prior to starting MAVENCLAD. Administer live-attenuated or live vaccines at least 4 to 6 weeks prior to starting MAVENCLAD due to risk of infection.
- **Hematologic Toxicity:** In addition to lymphopenia, decreases in other blood cells and hematological parameters have been reported with MAVENCLAD in clinical studies. Obtain complete blood count (CBC) with differential including lymphocyte count before and during treatment, periodically thereafter, and when clinically indicated.
- **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. In patients who require blood transfusion, irradiation of cellular blood components is recommended.
- **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 MAVENCLAD if clinically significant liver injury is suspected.
- **Hypersensitivity:** 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. Instruct patients to seek medical advice if they experience symptoms of cardiac failure (e.g., shortness of breath, rapid or irregular heartbeat, swelling).

Adverse Reactions: The most common adverse reactions (incidence of >20%) are upper respiratory tract infection, headache, and lymphopenia.

Drug Interactions: Concomitant use 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. Monitor for additive effects on the hematological profile with use of hemotoxic drugs. Avoid concomitant use of 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 >65 years, pregnant or breastfeeding women. Use in patients with moderate to severe renal or hepatic impairment is not recommended.

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

Please click **here** to view full Prescribing Information, including **BOXED WARNINGS.**

US-MAV-02188 07/24

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