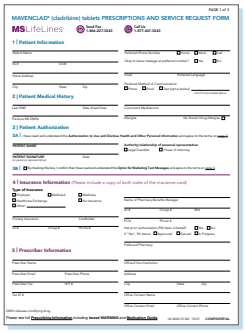
MAVENCLAD®
(cladribine) tablets 10 mg

Getting patients started with MAVENCLAD

Instructions for completing the MAVENCLAD Service Request Form (SRF)



DOWNLOAD THE SRF

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. 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** on the back cover and the accompanying full **Prescribing Information**, including **boxed WARNING** for additional information.

DOWNLOAD THE SRF

SRF PAGE 1 INSTRUCTIONS

MAVENCLAD® (cladribine) tablets PRESCRIPTIONS AND SERVICE REQUEST FORM

MSLifeLines®

Send Fax
1-866-227-3243

Call Us
1-877-447-3243

1 | Patient Information

Patient Name

Preferred Phone Number ☐ Home ☐ Work ☐ Cell

SS # DOB

Okay to leave message at preferred number? ☐ Yes ☐ No

Home Address

Email Preferred Language

City State Zip

Preferred Method of Communication
☐ Phone ☐ Email ☐ Text (opt-in below) _____
Cell if not provided above

2 | Patient Medical History

Last DMD Date of Last Dose

Concurrent Medications

Previous MS DMDs

Allergies No Known Drug Allergies ☐

3 | Patient Authorization

3A | 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

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

PATIENT SIGNATURE
(or personal representative)

Date

3B | ☐ 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 3.

Obtain patient signature here.

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

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

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

Name of Pharmacy Benefits Manager

ID # Group # BIN

Primary Insurance Cardholder

PCN Phone #

ID # Group # Phone #

Has prior authorization (PA) been initiated? ☐ Yes ☐ No
If "Yes", PA status: ☐ Approved ☐ Denied ☐ In Progress

Preferred Pharmacy

5 | Prescriber Information

Prescriber Name

Office/Clinic/Institution

Prescriber Email Prescriber Phone

Address

Prescriber Fax NPI #

City State Zip

Include all prescriber information, including NPI #.

Tax ID #

Office Contact Name

Office Contact Email Office Contact Phone

DMD=disease-modifying drug

Please see full **Prescribing Information** including **boxed WARNING** and **Medication Guide**.

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SRF PAGE 2 INSTRUCTIONS

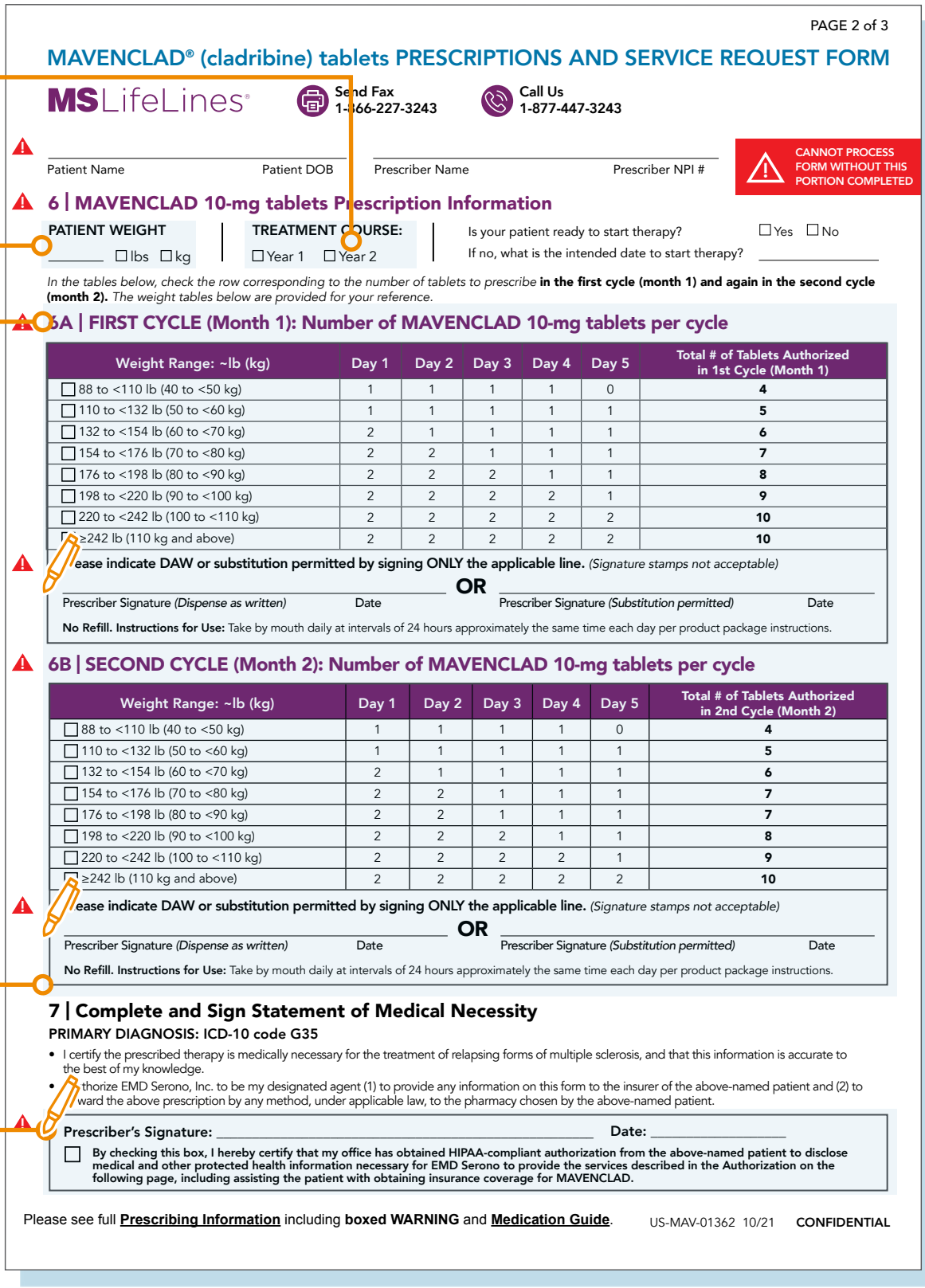
Please indicate if this is for year 1 or year 2. An SRF is required for each year.

Enter the patient's weight and indicate pounds OR kilograms.

Complete both 6A (Month 1) and 6B (Month 2) for this Treatment Year:

- **Check the row** corresponding to the number of tablets to prescribe
- **Ensure the prescriber signs either "Dispense as written" or "Substitution permitted"** for **both** the First Cycle (Month 1) and the Second Cycle (Month 2)

Prescriber signature here.



PAGE 2 of 3

MAVENCLAD® (cladribine) tablets PRESCRIPTIONS AND SERVICE REQUEST FORM

MSLifeLines®

Send Fax 1-866-227-3243

Call Us 1-877-447-3243

Patient Name _____ Patient DOB _____ Prescriber Name _____ Prescriber NPI # _____

CANNOT PROCESS FORM WITHOUT THIS PORTION COMPLETED

6 | MAVENCLAD 10-mg tablets Prescription Information

PATIENT WEIGHT _____ ☐ lbs ☐ kg

TREATMENT COURSE: ☐ Year 1 ☐ Year 2

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

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).** *The weight tables below are provided for your reference.*

6A | FIRST CYCLE (Month 1): Number of MAVENCLAD 10-mg tablets per cycle

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

Please indicate DAW or substitution permitted by signing ONLY the applicable line. *(Signature stamps not acceptable)*

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.

6B | SECOND CYCLE (Month 2): Number of MAVENCLAD 10-mg tablets per cycle

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

Please indicate DAW or substitution permitted by signing ONLY the applicable line. *(Signature stamps not acceptable)*

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.

7 | Complete and Sign Statement of Medical Necessity

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 method, under applicable law, to the pharmacy chosen by the above-named patient.

Prescriber's Signature: _____ **Date:** _____

☐ **By checking this box, I hereby certify that my office has obtained HIPAA-compliant authorization from the above-named patient to disclose medical and other protected health information necessary for EMD Serono to provide the services described in the Authorization on the following page, including assisting the patient with obtaining insurance coverage for MAVENCLAD.**

Please see full **Prescribing Information** including **boxed WARNING** and **Medication Guide**.

US-MAV-01362 10/21 **CONFIDENTIAL**

DOWNLOAD THE SRF

SRF PAGE 3 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, One Technology Place, Rockland, MA 02370. 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 3: Patient Authorization on page 1, including signature line.

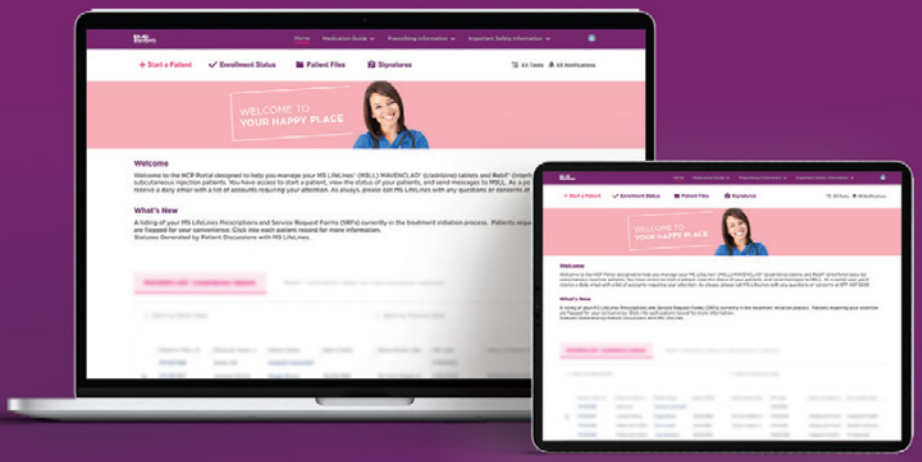
Opt-In for Automated Marketing Text Messages

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, One Technology Place, Rockland, MA 02370.

To authorize your consent, please check the box listed in Step 3: 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 now prescribe MAVENCLAD online via the MS LifeLines® Pro Portal

There you can:

- Start and submit a patient prescription for EMD Serono MS products
- Receive timely updates and alerts of patient status updates
- Send messages to the MS LifeLines team
- Gain a detailed view of the status of all your RMS patients receiving an EMD Serono MS product in one place

LEAVE PAPERWORK BEHIND—VISIT MSLIFELINESPRO.COM

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

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. 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. 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 full Prescribing Information, including **boxed WARNING** for additional information.

EMD Serono, Inc., One Technology Place, Rockland, MA 02370
US-MAV-01427 12/21

EMD SERONO