MAYZENT® (siponimod)
Prescription Start Form

MAYZENT®
(siponimod) tablets
0.25 mg • 2 mg

☐ New Patient ☐ Restarting Treatment ! **CANNOT BE PROCESSED UNLESS ALL FIELDS WITH THIS MARK ARE COMPLETED**

THE INFORMATION ON THIS PAGE SHOULD BE FILLED IN BY THE PATIENT OR HIS/HER CARE PARTNER

1 PATIENT INFORMATION

! First Name: _____

! Last Name: _____

Sex: ☐ Male ☐ Female

! Date of Birth: _____ /_____ /_____ (MM/DD/YYYY)

Address (no PO boxes): _____

City: _____ State: _____ ZIP: _____

E-mail is recommended to enroll in co-pay support:

_____

! Home Phone: _____-_____-_____

! Cell Phone: _____-_____-_____

The best time to call is: ☐ Morning ☐ Afternoon ☐ Evening

Contact Preferences (check all that apply):

☐ Home Phone ☐ Cell Phone ☐ E-mail ☐ Text

☐ OK to leave MAYZENT/Alongside MS™ voicemails

Preferred Language:

☐ English ☐ Spanish ☐ Other: _____

Please contact: ☐ Me ☐ My care partner (see below)

2 CARE PARTNER INFORMATION (if applicable)

First Name: _____

Last Name: _____

Relationship to Patient: _____

Guardian and/or Power of Attorney: ☐ Yes ☐ No

E-mail: _____

Home Phone: _____-_____-_____

Cell Phone: _____-_____-_____

Contact Preferences (check all that apply):

☐ Home Phone ☐ Cell Phone ☐ E-mail ☐ Text

3 INSURANCE INFORMATION (include a copy of both sides of all cards, including secondary insurance)

Primary Insurance

Insurance Carrier: _____

Cardholder Name: _____

Cardholder ID Number: _____

Group Number: _____

Secondary Insurance

Insurance Carrier: _____

Cardholder Name: _____

Cardholder ID Number: _____

Group Number: _____

Prescription Insurance

Prescription Insurance Carrier: _____

Cardholder Name: _____

Cardholder ID Number: _____

Rx Group Number: _____

Rx BIN Number: _____

Rx PCN Number: _____

REQUIRED PATIENT AUTHORIZATION AND ADDITIONAL CONSENTS

I have read and agree to the Patient Authorization, which includes sharing of genetic information (please see page 4).

! Patient Signature (not care partner): _____

! Date of Signature: _____ /_____ /_____ (MM/DD/YYYY)

☐ MAYZENT Co-Pay Program: I have read and agree to the Terms and Conditions for participation (please see page 6)

☐ Receiving text messages and calls: I have read and agree to receive text messages and calls as explained in the Telephone Consumer Protection Act (TCPA) Consent (optional, please see page 6)

☐ I have read and agree to the Fair Credit Reporting Act (FCRA) Authorization (optional, please see page 6)

FOR QUESTIONS, CALL
1-877-MAYZENT (1-877-629-9368)
24 hours a day, 7 days a week

Please see Important Safety Information on pages 7-8 and click here for full Prescribing Information, including Medication Guide.

THE INFORMATION ON THIS PAGE SHOULD BE FILLED IN BY THE PRESCRIBER

Patient's Name: _____ Date of Birth: ____/____/____ (MM/DD/YYYY)

! Diagnosis: ☐ ICD-10:G35 ☐ Other: _____

☐ Active SPMS ☐ CIS/RRMS

4 PRESCRIBING PHYSICIAN INFORMATION

! First Name: _____ Office Contact Name: _____

! Last Name: _____ Office Contact Phone: ____-____-____

Business/Practice Name: _____ ! Fax: ____-____-____

! Address: _____ E-mail: _____

! City: _____ ! State Medical License #: _____

! State: _____ ! ZIP: _____ ! NPI #: _____

5 ASSESSMENT SUPPORT

Assistance requested from Alongside MS™*† (check all that apply):

Blood Tests: ☐ CBC ☐ LFTs (transaminase & bilirubin) ☐ VZV antibody serology ☐ Genotype CYP2C9‡

Cardiac Evaluation: ☐ Electrocardiogram (ECG) ☐ Loaner ECG machine requested for in-office use§

Eye Exam: ☐ Macular edema screening‖

Observation Period:

☐ Assistance requested with first-dose observation (FDO) (recommended for patients with certain preexisting cardiac conditions)¶

Location of patient assessments: ☐ Program-sponsored medical facility and/or the patient's home

No assistance required and I confirm:

☐ The following tests are completed or not required for this patient: CBC, LFTs (transaminase & bilirubin), VZV antibody serology, genotype CYP2C9 (to determine dose),‡ ECG, and a macular edema screening

☐ FDO not required for patient (no relevant cardiac risk history)¶

☐ FDO required (recommended for patients with certain preexisting cardiac conditions)¶ and will be performed outside of Alongside MS

Ship treatment initiation product for FDO to: ☐ Prescribing office ☐ FDO location below

Health care provider: _____ Office Contact Phone: ____-____-____

Address: _____ City: _____ State: _____ ZIP: _____

*A benefits investigation to determine eligibility for certain support services will be completed even if assistance for treatment-related assessments are not requested.

†Free for commercially insured patients and those without insurance who are starting or restarting MAYZENT. Covered medical assessments include recommended blood tests, macular edema screening, electrocardiogram (ECG) and first-dose observation (FDO), as prescribed, provided via a Program-sponsored medical facility or at home. Macular edema screening is available in select areas only. Health care professionals overseeing FDO will evaluate preexisting conditions or concomitant medications that may preclude the patients from completing their FDO. This offer is not valid for medical assessments (i) performed in RI, (ii) for which payment may be made in whole or in part under federal or state health care programs, including but not limited to Medicare or Medicaid or (iii) where prohibited by law. There is a cash-pay option for residents of RI choosing to use a Program-sponsored medical facility. No purchase required. This Program is subject to termination or modification at any time. Medicare is accepted at some Program-sponsored facilities.

‡An FDA-cleared or -approved test for the detection of CYP2C9 variants to direct the use of siponimod is not currently available.

§The ECG equipment and over-read services provided in connection with the MAYZENT ECG Access Program may be used solely for MAYZENT patients undergoing a cardiac evaluation and/or first-dose observation (FDO). Limitations apply. See Health Care Provider Certification, which will be provided by CardioNet. Program is subject to termination or modification at any time. CardioNet does not make any treatment recommendations with respect to MAYZENT. The decision to start therapy with MAYZENT and the determination whether a patient is appropriate for discharge following the FDO should be made by the physician who is conducting the FDO in accordance with his or her clinical judgment.

‖An ophthalmic evaluation of the fundus, including the macula, is recommended in all patients before starting treatment.

¶Sinus bradycardia, first- or second-degree [Mobitz type I] AV block, or a history of myocardial infarction or heart failure.

CONTINUED ON THE NEXT PAGE

FOR QUESTIONS, CALL
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24 hours a day, 7 days a week

Please see Important Safety Information on pages 7-8 and click here for full Prescribing Information, including Medication Guide.

THE INFORMATION ON THIS PAGE SHOULD BE FILLED IN BY THE PRESCRIBER

Patient's Name: _____ Date of Birth: _____ /_____ /_____ (MM/DD/YYYY)

6 RX INFORMATION

The recommended maintenance dose of MAYZENT® (siponimod) tablets is 2 mg* taken orally once daily. These prescriptions are to facilitate patient initiation and allow for insurance processing. The first month's supply of MAYZENT will not be dispensed until after CYP2C9 genotype results are available and prescriber confirms or changes the patient's dose.

Treatment Initiation†

For **2 mg** maintenance dose patients:

☐ Free Starter Pack†: for patients who will titrate to a 2 mg maintenance dosage. Refills: 1 additional Starter Pack

Day 1: 1 x 0.25 mg | **Day 2:** 1 x 0.25 mg | **Day 3:** 2 x 0.25 mg | **Day 4:** 3 x 0.25 mg | **Day 5:** 5 x 0.25 mg

☐ MAYZENT Free First-Month Supply†

2 mg, 1 tablet taken orally once a day. Dispense 1 bottle (30 tablets/bottle)

For **1 mg** maintenance dose patients:

☐ Dispense 4 bottles of 0.25 mg tablets (28 tablets/bottle). No refills

Day 1: 1 x 0.25 mg | **Day 2:** 1 x 0.25 mg | **Day 3:** 2 x 0.25 mg | **Day 4:** 3 x 0.25 mg | **Day 5 and every day after:** 4 x 0.25 mg

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Bridge to Commercial Coverage of MAYZENT‡ (optional for commercially insured patients only)

Dispense the maintenance dose of MAYZENT directly from Homescripts™ at no cost to the patient (check only 1 box):

☐ 2 mg, 1 tablet taken orally once a day. Dispense 1 bottle (30 tablets/bottle), then 11 refills, or ____ months supply

☐ 1 mg, four 0.25-mg tablets taken orally once a day. Dispense 4 bottles (28 tablets/bottle), then 11 refills, or ____ months supply, 1 refill = 4 bottles

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Ongoing Prescription

Dispense (check only 1 box):

☐ 2 mg, 1 tablet taken orally once a day. Dispense 1 bottle (30 tablets/bottle), then 11 refills, or ____ months supply

☐ 1 mg, four 0.25-mg tablets taken orally once a day. Dispense 4 bottles (28 tablets/bottle), then 11 refills, or ____ months supply, 1 refill = 4 bottles

Specialty Pharmacy (optional): _____ (See Sales Specialist for network pharmacy list.)

REQUIRED SIGNATURE AND PHYSICIAN ATTESTATION

You must authorize these instructions by signing at the end of this section. We cannot process this form without your signature.

I certify the above therapy is medically necessary and this information is accurate to the best of my knowledge. I certify I am the physician who has prescribed MAYZENT to the previously identified patient and I provided the patient with a description of Alongside MS™. For the purposes of transmitting these prescriptions, I authorize NPAF, Novartis Pharmaceuticals Corporation, and its affiliates, business partners, and agents to forward as my agent for these limited purposes these prescriptions electronically, by facsimile, or by mail to the appropriate dispensing pharmacies. I will not attempt to seek reimbursement for free product provided to me for purposes of performing a first-dose observation.

☐ I have read and agree to the Prescriber Authorization for the NPAF on page 6.

Prescriber Signature: _____

Date of Signature: _____ /_____ /_____ (MM/DD/YYYY)

ATTN: New York prescribers, please submit prescription on original New York state prescription form.

*For patients with a CYP2C9*1*3 or *2*3 genotype, the recommended maintenance dose of MAYZENT is 1 mg once daily (4 x 0.25 mg). For treatment initiation in these patients, the first month's supply should be used. MAYZENT should not be used in patients with a CYP2C9*3*3 genotype. An FDA-cleared or -approved test for the detection of CYP2C9 variants to direct the use of siponimod is not currently available.

†For all patients prescribed a 2 mg maintenance dose of MAYZENT, a 5-day starter pack and one month of maintenance supply are available at no cost when starting or restarting therapy. To avoid an unintended lapse in therapy, patients insured through federal or state health care programs will receive this free medication after confirmation of insurance coverage for MAYZENT. Patients prescribed a 1 mg maintenance dose with either commercial insurance or without any insurance are eligible for their first month's supply when starting or restarting MAYZENT at no cost. Patients will self-titrate to their 1 mg maintenance dose using their first month's supply. Patients prescribed a 1 mg maintenance dose and whose prescriptions are paid for in whole or in part by a federal or state health care program are not eligible for this offer. No purchase required. Free medication will be dispensed by the MAYZENT Program Pharmacy, Homescripts, to the patient or to the health care provider overseeing the first dose observation, as directed. This offer is not health insurance and may not be submitted for insurance reimbursement. Limitations may apply. Novartis reserves the right to rescind, revoke, or amend the Program and discontinue support at any time without notice.

‡Eligible patients must have commercial insurance and a valid prescription for MAYZENT. By participating, patient acknowledges intent to pursue insurance coverage for MAYZENT with their health care provider. Program requires the submission of a request for coverage within 9 months post-Program initiation in order to remain eligible. Patients will receive their maintenance drug supply each month for up to 12 months or until they receive insurance coverage approval, whichever occurs earlier. Program is not available to patients who are uninsured or whose medications are reimbursed in whole or in part by Medicare, Medicaid, TRICARE, or any other federal or state program, or where prohibited by law. Patients may be asked to reverify insurance coverage status during the course of the Program. No purchase necessary. Program is not health insurance, nor is participation a guarantee of insurance coverage. Other limitations may apply. Novartis reserves the right to rescind, revoke, or amend the Program and discontinue support at any time without notice.

Please read the following carefully, then check the box where indicated on the previous pages.

Patient Authorization. I give permission for my health care providers (HCPs), pharmacies, service providers, and their contractors ("Health Care Providers"), health insurer(s) and their contractors ("Insurers"), and third-party contractors, to disclose my personal information, including information about my insurance benefits, prescriptions, my medical condition and history, **genetic information, including the results of genetic testing**, adherence to my treatment, and my general health ("Personal Information") to Novartis Pharmaceuticals Corporation, its affiliates, business partners, and agents, ("Novartis") and the Novartis Patient Assistance Foundation, Inc. ("NPAF") (collectively, "the Companies") so that the Companies may: (i) help to verify or coordinate insurance coverage or otherwise obtain payment for my treatment with MAYZENT, (ii) coordinate my receipt of and payment for MAYZENT, (iii) facilitate my access to MAYZENT, (iv) provide me with information about Novartis products, disease education and management programs, and promotional materials, (v) if I am eligible, coordinate the MAYZENT Co-pay Program, including managing and communicating with me about the co-pay support options available to me, (vi) provide me with medication reminders and support, (vii) conduct quality assurance, surveys, and other internal business activities in connection with the Alongside MS™ Program and other related programs, and (viii) if I am eligible for programs offered by the NPAF, to administer those programs, to send me information about programs that might help me pay for medicines, and to coordinate or share my Personal Information with my health care providers, other programs that might help me pay for medicines, government agencies, and insurance companies for purposes of providing or facilitating this assistance.

I give permission to the Companies to disclose my Personal Information to my Health Care Providers, insurer(s), caregivers, and other third-party contractors or service providers for the purposes described above. I also give permission to the Companies to combine or aggregate any information collected from me with information the Companies may collect about me from other sources for the purpose of providing or administering Program services.

I understand that some of my pharmacies or other health care providers may receive payment from the Companies depending on my enrollment or participation in therapy support services such as prescription refill reminders. I understand that once my Personal Information is disclosed, including my Protected Health Information, it may no longer be protected by federal privacy law and applicable state laws. Even though HIPAA may no longer apply, the Companies safeguard patient data through reasonable security measures and will use and share it only for the purposes specified in this Authorization.

I understand that I may refuse to sign this Authorization. I also may revoke (cancel) or get a copy of this Authorization at any time by calling 1-877-MAYZENT (1-877-629-9368) or by writing to the Customer Interaction Center, Novartis Pharmaceuticals Corporation, One Health Plaza, East Hanover, NJ 07936-1080. If I cancel my consent, I will no longer qualify for the services described. I also understand that if a Health Care Provider or Insurer is disclosing my Personal Information to the Companies on an authorized, ongoing basis, my cancellation with the Companies will be effective with respect to any such Health Care Provider or Insurer as soon as they receive notice of my cancellation.

Please see Important Safety Information on pages 7-8 and click here for full Prescribing Information, including Medication Guide.

Patient Authorization (cont)

My refusal or future revocation will not affect my medical treatment or insurance benefits; however, if I revoke this authorization, I may no longer be able to participate in the Alongside MS™ Program and related programs. If I revoke this Authorization, the Companies will stop using or sharing my information (except as necessary to end my participation in the Program), but my revocation will not affect uses and disclosures of Personal Information previously disclosed in reliance upon this Authorization. I understand that this Authorization will remain valid for 5 years after the date of my signature, unless I revoke it earlier. I also understand that the Alongside MS Program may change or end at any time without prior notification. I understand that I am entitled to receive a copy of this Patient Authorization.

I agree that my Personal Information provided on this form, including my mail, e-mail, and telephone number, may be used to contact me for all non-marketing purposes described in this Patient Authorization. I also agree that the Companies and others on its behalf, may use my Personal Information, and specifically including the number(s) provided on this form, to contact me via telephone calls and text messages made by or using automatic telephone dialing machines or artificial or prerecorded voice for all non-marketing purposes, including but not limited to sending me materials and asking for my participation in surveys.

I confirm that I am the subscriber for the telephone number(s) provided and the authorized user for the e-mail address(es) provided, and I agree to notify the Companies promptly if any of my number(s) or address(es) change in the future. I understand that my wireless service provider's message and data rates may apply.

I understand that the Companies do not permit my Personal Information to be used by their business partners for their own separate marketing purposes. I understand and agree that Personal Information transmitted by e-mail and cell phone cannot be secured against unauthorized access. In addition, I understand that my Personal Information may be accessed outside of the United States.

Please see Important Safety Information on pages 7-8 and click here for full Prescribing Information, including Medication Guide.

Please read the following carefully, then check the box where indicated on the previous pages.

Telephone Consumer Protection Act (TCPA) Consent

I consent to receive marketing calls and texts from and on behalf of the Novartis Group and NPAF, made with an auto-dialer or prerecorded voice, at the phone number(s) provided. I understand that my consent is not required or a condition of purchase. Number of messages will vary based on your Program selections. Message and data rates may apply. I understand that I can read the full Novartis Pharmaceuticals Corporation Privacy Policy at **www.usprivacy.novartis.com**. Text STOP to opt out and HELP for help.

MAYZENT Co-pay Program Terms and Conditions

Limitations apply. Valid only for those with private insurance. The Program includes the Co-Pay Card, Payment Card (if applicable), and Rebate, with a combined annual limit of $18,000. Patient is responsible for any costs once limit is reached in a calendar year. Program not valid (i) under Medicare, Medicaid, TRICARE, VA, DoD, or any other federal or state health care program, (ii) where patient is not using insurance coverage at all, or (iii) where the patient's insurance plan reimburses for the entire cost of the drug. The value of this Program is exclusively for the benefit of patients and is intended to be credited toward patient out-of-pocket obligations and maximums, including applicable co-payments, coinsurance, and deductibles. Program is not valid where prohibited by law. Patient may not seek reimbursement for the value received from this Program from other parties, including any health insurance program or plan, flexible spending account, or health care savings account. Patient is responsible for complying with any applicable limitations and requirements of their health plan related to the use of the Program. Valid only in the United States and Puerto Rico. This Program is not health insurance. Program may not be combined with any third-party rebate, coupon, or offer. Proof of purchase may be required. Novartis reserves the right to rescind, revoke, or amend the Program and discontinue support at any time without notice.

Fair Credit Reporting Act (FCRA) Authorization

I understand that I am providing “written instructions” authorizing NPAF and its vendor, under the FCRA, to obtain information from my credit profile or other information from the vendor, solely for the purpose of determining financial qualifications for programs administered by NPAF. I understand that I must affirmatively agree to these terms in order to proceed in this financial screening process.

Prescriber Authorization for the Novartis Patient Assistance Foundation, Inc. (NPAF)

I certify that any medication received will be used only for the patient named on this form and will not be offered for sale, trade, or barter. Further, no claim for reimbursement will be submitted concerning this medication, nor will any medication be returned for credit. I acknowledge that NPAF is exclusively for purposes of patient care and not for remuneration of any sort. I understand that NPAF may revise, change, or terminate programs at any time.

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INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

MAYZENT® (siponimod) is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

IMPORTANT SAFETY INFORMATION

Contraindications

- Patients with a CYP2C9*3/*3 genotype
- In the last 6 months, experienced myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization, or Class III/IV heart failure
- Presence of Mobitz type II second-degree, third-degree atrioventricular block, or sick sinus syndrome, unless patient has a functioning pacemaker

Infections: MAYZENT may increase risk of infections with some that are serious in nature. Life-threatening and rare fatal infections have occurred.

Before starting MAYZENT, review a recent complete blood count (CBC) (ie, within 6 months or after discontinuation of prior therapy). Delay initiation of treatment in patients with severe active infections until resolved. Employ effective treatments and monitor patients with symptoms of infection while on therapy. Consider discontinuing treatment if patient develops a serious infection.

Cases of fatal cryptococcal meningitis (CM) were reported in patients treated with another sphingosine 1-phosphate (S1P) receptor modulator. Rare cases of CM have occurred with MAYZENT. If CM is suspected, MAYZENT should be suspended until cryptococcal infection has been excluded. If CM is diagnosed, appropriate treatment should be initiated.

No cases of progressive multifocal leukoencephalopathy (PML) were reported in MAYZENT clinical trials; however, they have been observed in patients treated with another sphingosine 1-phosphate (S1P) receptor modulator and other multiple sclerosis (MS) therapies. If PML is suspected, MAYZENT should be discontinued.

Cases of herpes viral infection, including one case of reactivation of varicella zoster virus leading to varicella zoster meningitis, have been reported. Patients without a confirmed history of varicella zoster virus (VZV) or without vaccination should be tested for antibodies before starting MAYZENT. If VZV antibodies are not present or detected, then VZV immunization is recommended and MAYZENT should be initiated 4 weeks after vaccination.

Use of live vaccines should be avoided while taking MAYZENT and for 4 weeks after stopping treatment.

Caution should be used when combining treatment (ie, anti-neoplastic, immune-modulating, or immunosuppressive therapies) due to additive immune system effects.

Macular Edema: In most cases, macular edema occurred within 4 months of therapy. Patients with history of uveitis or diabetes are at an increased risk. Before starting treatment, an ophthalmic evaluation of the fundus, including the macula, is recommended and at any time if there is a change in vision. The use of MAYZENT in patients with macular edema has not been evaluated; the potential risks and benefits to the individual patient should be considered.

Bradyarrhythmia and Atrioventricular Conduction Delays: Prior to initiation of MAYZENT, an ECG should be obtained to determine if preexisting cardiac conduction abnormalities are present. In all patients, a dose titration is recommended for initiation of MAYZENT treatment to help reduce cardiac effects.

MAYZENT was not studied in patients who had:

- In the last 6 months, experienced myocardial infarction, unstable angina, stroke, TIA, or decompensated heart failure requiring hospitalization
- New York Heart Association Class II-IV heart failure
- Cardiac conduction or rhythm disorders, including complete left bundle branch block, sinus arrest or sino-atrial block, symptomatic bradycardia, sick sinus syndrome, Mobitz type II second-degree AV-block or higher-grade AV-block (either history or observed at screening), unless patient has a functioning pacemaker
- Significant QT prolongation (QTc greater than 500 msec)
- Arrhythmias requiring treatment with Class Ia or Class III anti-arrhythmic drugs

Reinitiation of treatment (initial dose titration, monitoring effects on heart rate and AV conduction [ie, ECG]) should apply if ≥4 consecutive daily doses are missed.

Respiratory Effects: MAYZENT may cause a decline in pulmonary function. Spirometric evaluation of respiratory function should be performed during therapy if clinically warranted.

Liver Injury: Elevation of transaminases may occur in patients taking MAYZENT. Before starting treatment, obtain liver transaminase and bilirubin levels. Closely monitor patients with severe hepatic impairment. Patients who develop symptoms suggestive of hepatic dysfunction should have liver enzymes checked, and MAYZENT should be discontinued if significant liver injury is confirmed.

Increased Blood Pressure: Increase in systolic and diastolic pressure was observed about 1 month after initiation of treatment and persisted with continued treatment. During therapy, blood pressure should be monitored and managed appropriately.

Fetal Risk: Based on animal studies, MAYZENT may cause fetal harm. Women of childbearing potential should use effective contraception to

Please see additional Important Safety Information on page 8 and click here for full Prescribing Information, including Medication Guide.

IMPORTANT SAFETY INFORMATION (cont)

avoid pregnancy during and for 10 days after stopping MAYZENT therapy.

Posterior Reversible Encephalopathy Syndrome (PRES): Rare cases of PRES have been reported in patients receiving a sphingosine 1-phosphate (S1P) receptor modulator. Such events have not been reported for patients treated with MAYZENT in clinical trials. If patients develop any unexpected neurological or psychiatric symptoms, a prompt evaluation should be considered. If PRES is suspected, MAYZENT should be discontinued.

Unintended Additive Immunosuppressive Effects From Prior Treatment or After Stopping MAYZENT: When switching from drugs with prolonged immune effects, the half-life and mode of action of these drugs must be considered to avoid unintended additive immunosuppressive effects.

Initiating treatment with MAYZENT after treatment with alemtuzumab is not recommended.

After stopping MAYZENT therapy, siponimod remains in the blood for up to 10 days. Starting other therapies during this interval will result in concomitant exposure to siponimod.

Lymphocyte counts returned to the normal range in 90% of patients within 10 days of stopping therapy. However, residual pharmacodynamic effects, such as lowering effects on peripheral lymphocyte count, may persist for up to 3-4 weeks after the last dose. Use of immunosuppressants within this period may lead to an additive effect on the immune system, and therefore, caution should be applied 3-4 weeks after the last dose of MAYZENT.

Severe Increase in Disability After Stopping MAYZENT: Severe exacerbation of disease, including disease rebound, has been rarely reported after discontinuation of an S1P receptor modulator. The possibility of severe exacerbation of disease should be considered after stopping MAYZENT treatment, thus patients should be monitored upon discontinuation.

Most Common Adverse Reactions: Most common adverse reactions (>10%) are headache, hypertension, and transaminase increases.

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MAYZENT® (siponimod) tablets

NOVARTIS

Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080

3/19

T-AAF-1371772