MAYZENT®
(siponimod) tablets
0.25 mg • 2 mg

WHEN CHOOSING TREATMENT FOR PATIENTS WITH FIRST SIGNS OF PROGRESSION IN RMS AND ACTIVE SPMS[1]

EXPERIENCE MATTERS

MAYZENT® IS THE FIRST AND ONLY ORAL DMT studied and proven to delay disability progression in a more progressed RMS population, including active SPMS[1,2]*

DMT=disease-modifying therapy; EDSS=Expanded Disability Status Scale; RMS=relapsing multiple sclerosis; SPMS=secondary progressive MS.
*Patients in *EXPAND* had a mean EDSS score of 5.4.[3]

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

Please see complete Important Safety Information on pages 10-11 and accompanying full Prescribing Information.

EXPERIENCE MATTERS
MAYZENT® WAS PROVEN TO DELAY DISABILITY PROGRESSION IN A MORE PROGRESSED RMS POPULATION, INCLUDING aSPMS[1]

Sample profiles of patients:

*Not an actual patient.

JESS, 41 YEARS OLD*
Science teacher

"I worry that my RMS is starting to affect my teaching."

WHAT'S CHANGED IN THE LAST YEAR
- Trouble concentrating
- Difficulty organizing lesson plans
- Mild motor deficits, such as weakness in right leg (observed slight right foot drag)

PATIENT HISTORY
- **6 YEARS** since MS diagnosis
- **RELAPSES ARE LESS FREQUENT,** but last MRI revealed 1 new GdE lesion and an increase in T2 lesion volume
- **1 TREATMENT SINCE DIAGNOSIS**
- Initiated current oral medication 2 years ago

EDSS score: **3.5**

JAMIE, 48 YEARS OLD*
Accountant

"Walking my dog is something I used to look forward to, and now that I need a cane more often, I just can't do it."

WHAT'S CHANGED IN THE LAST YEAR
- Ambulatory difficulty
  - Can no longer take dog on walks
  - Intermittent use of cane
- Moderate urinary urgency
- Chronic fatigue
- Has trouble remembering words

PATIENT HISTORY
- **13 YEARS** since MS diagnosis
- **1 RELAPSE** in the past 2 years, last MRI showed 1 new GdE lesion and slow expansion of T2 lesion volume
- **2 TREATMENTS SINCE DIAGNOSIS**
- Initiated current oral medication 2 years ago

EDSS score: **5.5**

*Not an actual patient.

aSPMS=active secondary progressive MS; GdE=gadolinium-enhancing; MRI=magnetic resonance imaging; MS=multiple sclerosis.

IMPORTANT SAFETY INFORMATION (CONT)

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.

CLINICAL EXPERIENCE MATTERS
EXPAND STUDIED A BROAD RANGE OF DISABILITY—INCLUDING PATIENTS PREVIOUSLY TREATED WITH A DMT[3]

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MAYZENT was evaluated in *EXPAND*—the largest Phase III study of SPMS patients to date (N=1651)[4]

BASELINE PATIENT CHARACTERISTICS FOR PATIENTS ON MAYZENT[3]

Age (mean)	**48 YEARS** (Range: 21-61 years)	EDSS progression documented in the 2 years prior to study	**100%** of patients
Previous treatment	**78%** (n=860) had received a DMT	Patients with GdE lesions (%)	**21%** of patients
Time since onset of MS symptoms (mean)	**17 YEARS**	Patients with at least 1 relapse within the 2 years prior to study entry (%)	**36%** of patients
Time since initial MS diagnosis (mean)	**13 YEARS** (Range: 0-44 years)	EDSS score (mean)	**5.4** (Range: 3.0-6.5)

AT THE FIRST SIGNS OF PROGRESSION IN RMS AND ACTIVE SPMS, CHOOSE MAYZENT[1]

IMPORTANT SAFETY INFORMATION (CONT)

Infections (cont): If CM is suspected, MAYZENT should be suspended until cryptococcal infection has been excluded. If CM is diagnosed, appropriate treatment should be initiated.

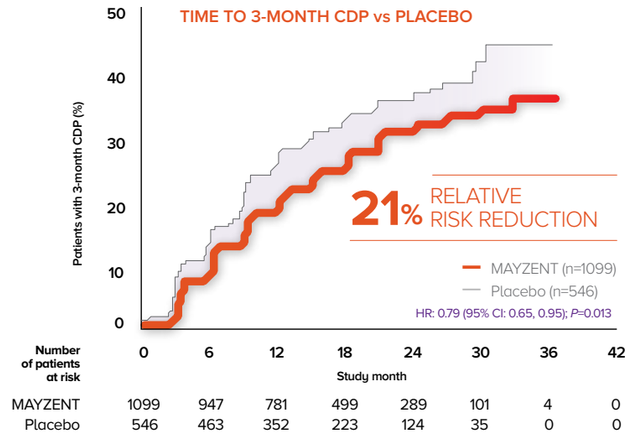
No cases of progressive multifocal leukoencephalopathy (PML) were reported in MAYZENT clinical trials; however, they have been observed in patients treated with another sphingosine 1-phosphate (S1P) receptor modulator and other multiple sclerosis (MS) therapies. If PML is suspected, MAYZENT should be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

Please see complete Important Safety Information on pages 10-11 and accompanying full Prescribing Information.

EFFICACY MATTERS

MAYZENT® WAS PROVEN TO DELAY DISABILITY PROGRESSION IN THE *EXPAND* CORE STUDY[3]

PRIMARY END POINT RESULTS[1]



- The proportion of patients with 3-month CDP for MAYZENT was 26% vs 32% for placebo[3]
- CDP was defined as a ≥1-point increase from baseline in EDSS score (0.5-point increase for patients with a baseline EDSS score of ≥5.5) sustained for 3 months[1]
- Although MAYZENT had a significant effect on CDP in patients with active SPMS (relapse in the 2 years prior to study entry), its effect in patients with nonactive SPMS was not statistically significant[1]

KEY SECONDARY END POINT RESULTS*

T25-FW TEST

Time to 3-month confirmed deterioration by ≥20% on the T25-FW test was not statistically significant vs placebo (*P*=NS)[1]

CNS TISSUE MEASURE: T2 LESION VOLUME

Reduced the expansion of T2 lesion volume at 12 and 24 months vs placebo (adjusted mean; *P*<0.01†)

- Change from baseline in T2 lesion volume: 184 mm^3 for patients on MAYZENT vs 879 mm^3 for placebo[1]

†Nominal *P* value, not corrected for multiple comparisons.

In *EXPAND*, a prespecified hierarchical analysis consisted of the primary end point and these 2 key secondary end points. The T25-FW test key end point was not significant; therefore, the T2 lesion volume key secondary end point was considered nominal. The remaining end points were not corrected for multiple comparisons.[1,3]

CDP=confirmed disability progression; CI=confidence interval; CNS=central nervous system; HR=hazard ratio; NS=not significant; T25-FW=timed 25-foot walk.

IMPORTANT SAFETY INFORMATION (CONT)

Infections (cont): 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.

LONG-TERM DATA MATTERS

SELECT EFFICACY ASSESSMENTS UP TO 5 YEARS WERE CONSISTENT WITH THE CORE STUDY[3,5‡]

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EXPAND OPEN-LABEL EXTENSION STUDY INTERIM EXPLORATORY DATA

The objective of the study is to evaluate the long-term safety and tolerability of MAYZENT. The extension study allows patients who completed the core part of the *EXPAND* study to continue with MAYZENT, and aims to provide long-term safety data, as well as evaluate exploratory long-term data on efficacy measures.

Of the 1224 patients who entered into the extension study from the core study, 593 (72.2%) of MAYZENT patients (continuous MAYZENT group) and 285 (71.4%) of placebo patients (placebo-switch group) continued into the extension. The mean exposure to MAYZENT for all patients (core + extension) was 39.4 months. 18.5% of all study patients (core + extension) reached the 5-year MAYZENT treatment milestone.[5]

SELECT LONG-TERM EXPLORATORY END POINTS AND ASSESSMENTS

TIME TO 6-MONTH CDP

22% RELATIVE RISK REDUCTION

- In this analysis, patients who started in the MAYZENT treatment arm experienced a greater reduction in the risk of disability progression vs patients who switched to MAYZENT later[5]

ANNUALIZED RELAPSE RATE

52% RELATIVE REDUCTION in ARR
vs placebo-switch group

- Defined as the average number of confirmed relapses per year (0.051 for continuous MAYZENT vs 0.106 for placebo-switch group)[5]

COGNITIVE PROCESSING SPEED

23% OVERALL REDUCTION in the risk of decrease in SDMT score
vs placebo-switch group

- SDMT was the only cognitive assessment conducted in the extension study[5]

The extension study end points differ from the core study and were predefined as exploratory in the extension protocol.[6]

SDMT was assessed but was not an exploratory end point in the extension study. Additional long-term data that was collected but not listed: 6-month confirmed worsening of at least 20% from baseline in the T25-FW test, MRI parameters, Multiple Sclerosis Walking Scale-12, and EuroQoL.[3,6]

These exploratory analyses represent chance findings. No conclusions of statistical or clinical significance can be drawn. Consider interim analysis open-label extension study limitations when interpreting data. The open-label extension study is not blinded, not controlled, and includes inherent self-selection bias for remaining in the trial.

ARR=annualized relapse rate; SDMT=Symbol Digit Modalities Test.
‡6-month CDP, ARR, and SDMT were exploratory end points and assessments of efficacy measurements, respectively, in the *EXPAND* extension study.[6]

IMPORTANT SAFETY INFORMATION (CONT)

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.

Please see complete Important Safety Information on pages 10-11 and accompanying full Prescribing Information.

EXPERIENCE MATTERS

DEMONSTRATED SAFETY PROFILE IN THE *EXPAND* CORE STUDY[1]

Adverse events that occurred in ≥5% of patients taking MAYZENT®, and at a rate ≥1% higher than in patients receiving placebo

PROPORTION OF PATIENTS WITH ADVERSE EVENTS

	MAYZENT 2 mg (n=1099)	Placebo (n=546)
Headache	15%	14%
Hypertension	13%	9%
Transaminase levels increased	11%	3%
Falls	11%	10%
Peripheral edema	8%	4%
Nausea	7%	4%
Dizziness	7%	5%
Diarrhea	6%	4%
Bradycardia	6%	3%
Pain in extremity	6%	4%

In the core study, the most common adverse events (incidence ≥10%) were headache (15%), hypertension (13%), and transaminase increases (11%).

Treatment discontinuation rates due to adverse events were similar across treatment arms.

- 8.5% of patients taking MAYZENT discontinued treatment due to adverse events vs 5.1% with placebo

WITH MAYZENT, lymphocytes are stored, not destroyed, in the lymph nodes. The half-life of MAYZENT is approximately 30 hours, and upon discontinuation, blood lymphocyte counts rapidly recover within 10 days*†

The mechanism by which siponimod exerts therapeutic effects on MS is unknown but may involve reduction of lymphocytes in the CNS.

*In 90% of patients.
†After stopping MAYZENT treatment, residual lowering of peripheral lymphocyte count may persist for up to 3-4 weeks after the last dose.

IMPORTANT SAFETY INFORMATION (CONT)

Macular Edema (cont): 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

EXPERIENCE MATTERS

THE SAFETY PROFILE OF MAYZENT REMAINED CONSISTENT WITH THE CORE STUDY UP TO 5 YEARS[5]

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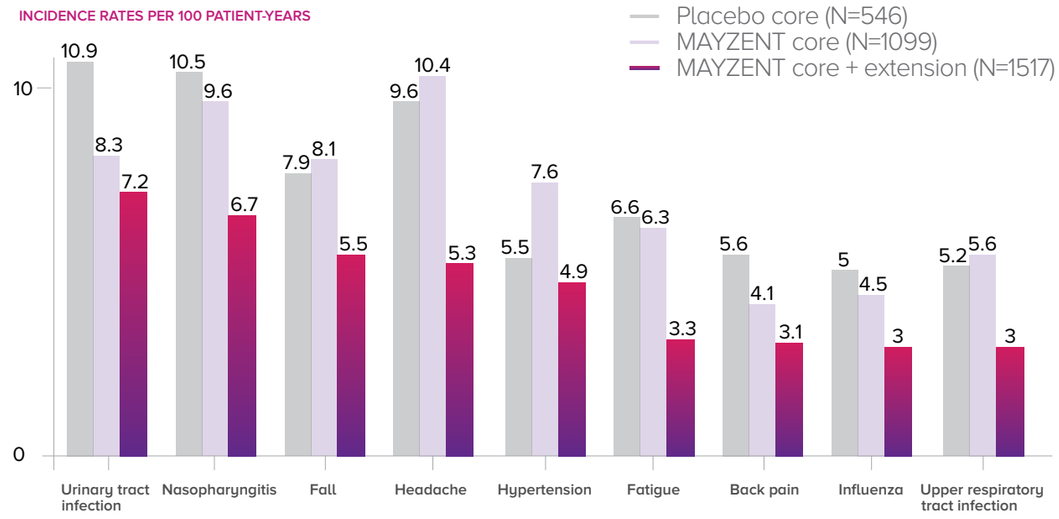
Adverse events that occurred in ≥3% of patients taking MAYZENT in the core and extension studies (analysis results were consistent with core study per listed criteria)

PROPORTION OF PATIENTS WITH ADVERSE EVENTS



IMPORTANT SAFETY INFORMATION (CONT)

Bradyarrhythmia and Atrioventricular Conduction Delays (cont):

MAYZENT was not studied in patients who had (cont):

- 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.

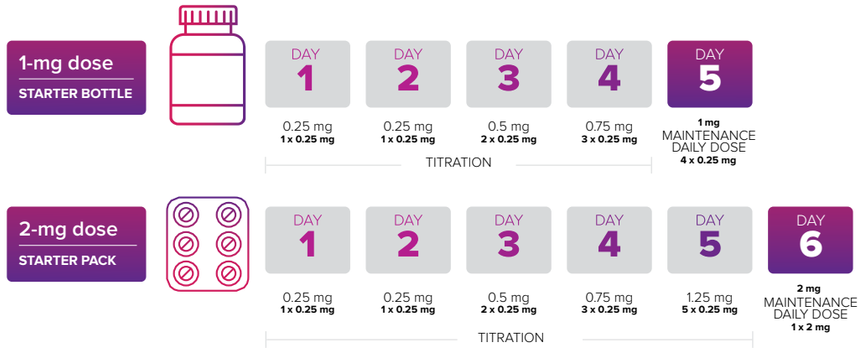
Respiratory Effects: MAYZENT may cause a decline in pulmonary function. Spirometric evaluation of respiratory function should be performed during therapy if clinically warranted.

Please see complete Important Safety Information on pages 10-11 and accompanying full Prescribing Information.

DOSING MATTERS

INITIATING TREATMENT WITH MAYZENT®—A ONCE-DAILY ORAL[1]

MAYZENT is an S1P receptor modulator with precisely determined dosing to fit your patient's distinct metabolism, as well as a tailored titration schedule to help patients safely reach their appropriate maintenance dose.[1]



CONSIDERATIONS FOR INITIATION

Genotype testing: Patients undergo a genotype test to identify their specific variant of CYP2C9, the principal enzyme that metabolizes MAYZENT.* This genotype test identifies the appropriate MAYZENT maintenance dose.[1]

Most patients won't require an FDO during initiation: An FDO is required only for patients with certain preexisting cardiac conditions.[1,7]

Titration schedule: Initiation of MAYZENT treatment results in a transient decrease in heart rate and atrioventricular conduction delays. For all patients, a dose titration is recommended for initiation of MAYZENT treatment to help patients safely reach their maintenance dose.[1]

FDO=first-dose observation; S1P=sphingosine 1-phosphate.
*Patients with a CYP2C9*3/*3 genotype should not be treated with MAYZENT.[1]

IMPORTANT SAFETY INFORMATION (CONT)

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.

Cutaneous Malignancies: Long-term use of S1P modulators, including MAYZENT, have been associated with an increased risk of basal cell carcinoma (BCC). Cases of other cutaneous malignancies, including melanoma and squamous cell carcinoma, have also been reported in patients treated with MAYZENT and in patients treated with another S1P modulator.

PATIENT ACCESS MATTERS

DEDICATED PATIENT SUPPORT WITH ALONGSIDE™ MAYZENT

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Alongside™ MAYZENT®

Our goal is to get your patients started seamlessly

Alongside MAYZENT is committed to providing the right support, right when your patients need it. We'll adapt to your process and your schedule—so you and your patients have clarity and know what to expect.

You can initiate enrollment in two ways, online or via fax—you can even get started on baseline assessments before submitting a Start Form.

Get your patients started on treatment in just 2 steps—assessments and initiation. Pick the program services that best fit your process.

STEP 1: ASSESSMENTS

STEP 2: TREATMENT INITIATION

ESTABLISHED PAYER COVERAGE FOR MAYZENT

MAYZENT provides broad managed care coverage with >85% approval rates across commercial and government insurance segments.[8]

IMPORTANT SAFETY INFORMATION (CONT)

Cutaneous Malignancies (cont): Periodic skin examination is recommended. Monitor for suspicious skin lesions and promptly evaluate any that are observed. Exposure to sunlight and ultraviolet light should be limited by wearing protective clothing and using a sunscreen with high protection factor. Concomitant phototherapy with UV-B radiation or PUVA-photochemotherapy is not recommended.

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.

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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.

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Contraindications

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- 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.

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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.

Cutaneous Malignancies: Long-term use of S1P modulators, including MAYZENT, have been associated with an increased risk of basal cell carcinoma (BCC). Cases of other cutaneous malignancies, including melanoma and squamous cell carcinoma, have also been reported in patients treated with MAYZENT and in patients treated with another S1P modulator.

Periodic skin examination is recommended. Monitor for suspicious skin lesions and promptly evaluate any that are observed. Exposure to sunlight and ultraviolet light should be limited by wearing protective clothing and using a sunscreen with high protection factor. Concomitant phototherapy with UV-B radiation or PUVA-photochemotherapy is not recommended.

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 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.

Please see accompanying full Prescribing Information, including Medication Guide.

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mayzenthcp.com

EXPERIENCE MATTERS
STAY AHEAD OF PROGRESSION—CHOOSE MAYZENT®[1,3]

- **FIRST AND ONLY ORAL DMT** studied and proven to delay disability progression in a more progressed RMS population, including active SPMS[1,2*]
- **DEMONSTRATED SAFETY PROFILE** in the largest trial designed for this more progressed patient population in RMS[1,4]
- **SELECT INTERIM ASSESSMENTS UP TO 5 YEARS WERE CONSISTENT** with the *EXPAND* core study, and patients who started in the MAYZENT treatment arm experienced a greater reduction in the risk of disability progression vs patients who switched to MAYZENT later[3,5†]
- **A ONCE-DAILY ORAL** with precisely determined dosing to fit your patient's distinct metabolism[1]
- **DEDICATED PATIENT ACCESS SUPPORT THAT BEST FITS YOUR PROCESS**
  Get your patients started on treatment in just 2 steps—assessments and initiation

*Patients in *EXPAND* had a mean EDSS score of 5.4.[3]
†6-month CDP, ARR, and SDMT were exploratory end points and assessments of efficacy measurements, respectively, in the *EXPAND* extension study.[6]

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References: 1. Mayzent [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; 2021. **2.** Data on file. First and only progressing RMS treatment. Novartis Pharmaceuticals Corp; January 2020. **3.** Kappos L, Bar-Or A, Cree BAC, et al; for the EXPAND Clinical Investigators. Siponimod versus placebo in secondary progressive multiple sclerosis (EXPAND): a double-blind, randomised, phase 3 study. *Lancet.* 2018;391(10127):1263-1273. **4.** Data on file. US National Library of Medicine. ClinicalTrials.gov. SPMS Clinical Trial Search Results. Accessed December 19, 2020. **5.** Data on file. Long-term Efficacy and Safety of Siponimod in Patients with SPMS: EXPAND Extension Analysis up to 5 Years. Novartis Pharmaceuticals Corp; May 2020. **6.** Data on file. A multicenter, randomized, double-blind, parallel-group, placebo-controlled variable treatment duration study evaluating the efficacy and safety of Siponimod (BAF312) in patients with secondary progressive multiple sclerosis followed by extended treatment with open-label BAF312. Novartis Pharmaceuticals Corp; July 2020. **7.** Data on file. Mayzent FDO Analysis. Novartis Pharmaceuticals Corp; 2020. **8.** Data on file. Mayzent approval rate analysis. Novartis Pharmaceuticals Corp; June 2020.

NOVARTIS

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East Hanover, New Jersey 07936-1080

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