In a 2-year study, people taking ZEPOSIA® (ozanimod) had 38% fewer relapses and 42% fewer new or enlarging lesions (T2) than those taking Avonex® (interferon beta-1a). There was no significant difference in disability progression between people taking ZEPOSIA and those taking Avonex.

ZEPOSIA® (ozanimod) is a prescription medicine used to treat relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

It is not known if ZEPOSIA is safe and effective in children under 18 years of age.

SELECTED IMPORTANT SAFETY INFORMATION

ZEPOSIA should not be taken if:

- You have or have had problems with your heart or blood flow such as:
  - A heart attack, chest pain (unstable angina), a stroke or mini-stroke (transient ischemic attack [TIA]), or certain types of heart failure in the last six months

Please see Important Safety Information on pages 16–22 and full Prescribing Information, including Medication Guide.

ZEPOSIA TREATS THE VISIBLE + INVISIBLE SIGNS OF MS SO YOU CAN BE THERE FOR THEM

With MS, there are signs that are visible and signs that aren't. Help protect yourself from both.

"VISIBLE" SIGNS OF MS

These signs can be **caused by MS relapses**. While your doctor can help identify these signs, others may see them, too.

"INVISIBLE" SIGNS OF MS

These are signs that may not be visible to others, but can be seen by you and your doctor on an MRI—**such as new or enlarging lesions**.

Ask your doctor about both the **visible + invisible** signs of MS.

MRI=magnetic resonance imaging.

SELECTED IMPORTANT SAFETY INFORMATION

ZEPOSIA should not be taken if: (cont'd)

- You have or have had problems with your heart or blood flow such as:
  - A history of certain types of irregular or abnormal heartbeat (arrhythmia) that is not corrected by a pacemaker
- You have untreated, severe breathing problems during your sleep (sleep apnea)
- You take certain medicines called monoamine oxidase (MAO) inhibitors (such as selegiline, phenelzine, linezolid)

Please see Important Safety Information on pages 16–22 and full Prescribing Information, including Medication Guide.

ONE PILL, ONCE A DAY

ZEPOSIA® (ozanimod) helps **protect the brain** from the damaging effects of MS by **reducing relapses and new or enlarging lesions**.*

ZEPOSIA is for adults. Take as directed by your doctor if certain liver problems exist.

*In a 2-year study, people taking ZEPOSIA had 38% fewer relapses and 42% fewer new or enlarging lesions (T2) than those taking Avonex® (interferon beta-1a). There was no significant difference in disability progression between people taking ZEPOSIA and those taking Avonex.

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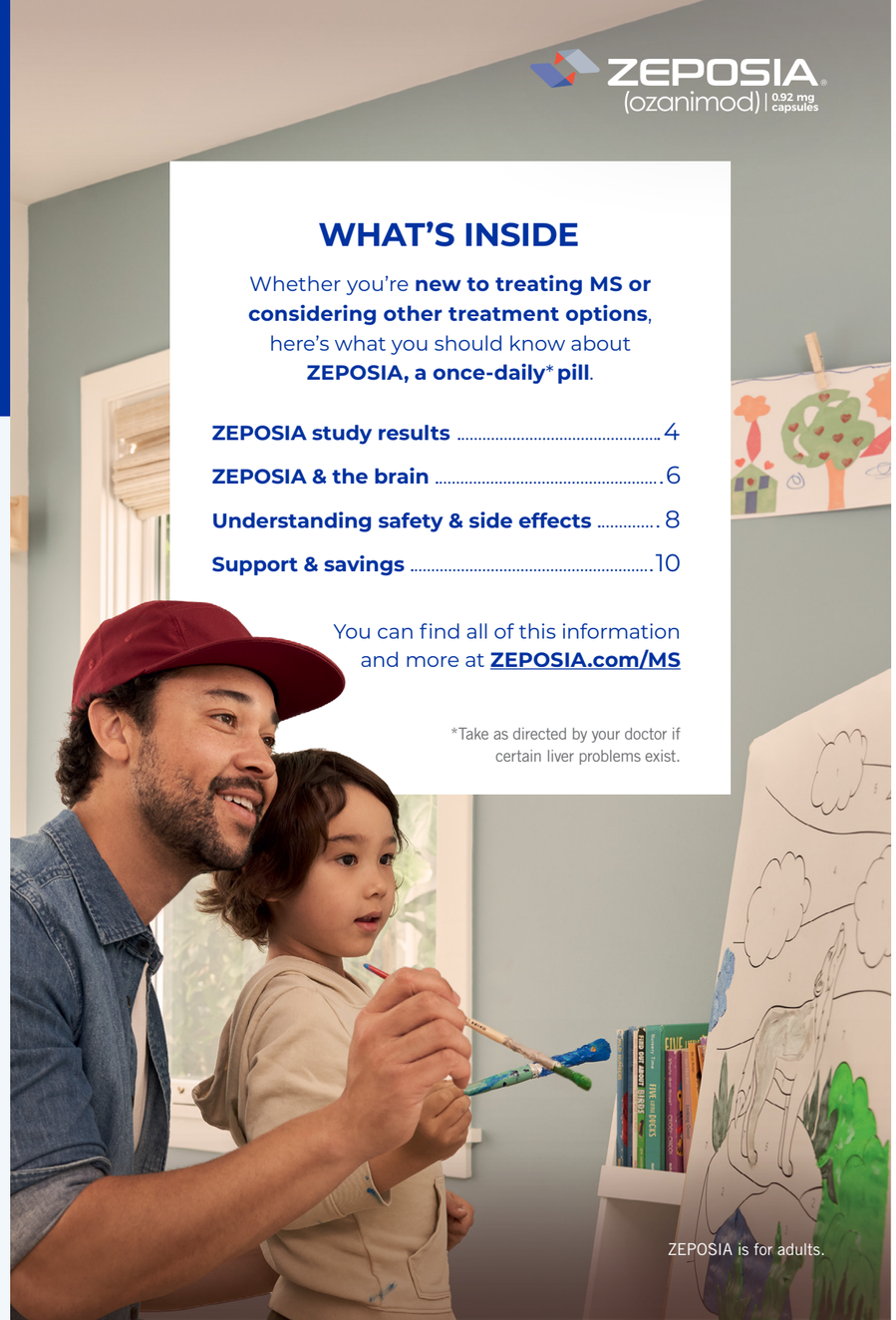

WHAT'S INSIDE

Whether you're **new to treating MS or considering other treatment options**, here's what you should know about **ZEPOSIA, a once-daily* pill**.

You can find all of this information and more at **ZEPOSIA.com/MS**

*Take as directed by your doctor if certain liver problems exist.

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What is ZEPOSIA?

ZEPOSIA is a prescription medicine used to treat:

Adults with relapsing forms of multiple sclerosis (MS), including:

- **C**linically **I**solated **S**yndrome (**CIS**),
- **R**elapsing-**R**emitting **MS** Disease (**RRMS**), and
- Active **S**econdary **P**rogressive **MS** Disease (**SPMS**)

Adults with moderately to severely active ulcerative colitis (UC)

What are the serious side effects of ZEPOSIA?

ZEPOSIA may cause serious side effects. A serious side effect is a side effect that can sometimes become life threatening and can lead to hospitalization or death.

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including:

- Infections
- Progressive multifocal leukoencephalopathy (PML)
- Slow heart rate (also known as bradyarrhythmia)
- Liver problems
- Increased blood pressure
- Breathing problems
- Macular edema
- Types of skin cancer
- Swelling and narrowing of blood vessels in your brain

If you take or have previously taken ZEPOSIA for multiple sclerosis (MS):

You may have severe worsening of MS symptoms after stopping ZEPOSIA. Your symptoms of MS may return and become worse compared to before or during treatment.

What are the most common side effects?

The most common side effects of ZEPOSIA can include:

- Upper respiratory tract infection
- Elevated liver enzymes
- Sudden drops in blood pressure when you stand up (orthostatic hypotension)
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These are not all of the possible side effects of ZEPOSIA.

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ZEPOSIA (ozanimod) | 0.92 mg capsules

ZEPOSIA is proven to reduce relapses and active lesions

ZEPOSIA® (ozanimod) was compared to a leading injectable medicine, Avonex® (interferon beta-1a), in 2 separate clinical studies (over 1 year and 2 years). When these 2 studies were completed (and combined), they were **one of the largest studies to compare one MS medication to another** (not a placebo). They included 1,769 people: 880 who took ZEPOSIA and 889 who took Avonex.

What is a relapse?

When a new MS symptom occurs, or an existing symptom gets worse, it's defined as a "relapse" (or "exacerbation" or "flare-up"). This symptom must last more than 24 hours and be separated from the previous relapse by at least 30 days. The severity and duration of a relapse are often unpredictable. **No 2 relapses are alike**, but most last from a few days to several months.

What are lesions?

An MS lesion is an area of damage or scarring that can occur throughout the central nervous system, including the brain. Lesions often progress over time, and this progress is monitored by your doctor using magnetic resonance imaging (MRI) scans.

"It's been over a year now, and ZEPOSIA is working well for me. My doctor is happy with the results.

–Melissa
Real ZEPOSIA patient
(Compensated for her time)

Individual results may vary.

ZEPOSIA (ozanimod) 0.92 mg capsules

ZEPOSIA WAS PROVEN SUPERIOR VS AVONEX*

	1-year study	2-year study
RELAPSES	**48% fewer relapses** **78% had zero relapses** vs 66% of people taking Avonex	**38% fewer relapses** **76% had zero relapses** vs 64% of people taking Avonex
NEW OR ENLARGING LESIONS (T2)	**48% fewer lesions** 1.47 average per year vs 2.84 with Avonex	**42% fewer lesions** 1.84 average per year vs 3.18 with Avonex
ACTIVE LESIONS (T1 Gd-ENHANCING)	**63% fewer lesions** 0.16 average per year vs 0.43 with Avonex	**53% fewer lesions** 0.18 average per year vs 0.37 with Avonex

3 out of 4 patients taking
ZEPOSIA had ZERO RELAPSES
in both clinical studies†

NO CONFIRMED PROGRESSION OF PHYSICAL DISABILITY

Combined from both studies at 2 years

90% of people taking ZEPOSIA or Avonex had
no confirmed DISABILITY PROGRESSION
(as defined in studies)

There was no significant difference in disability progression between people taking ZEPOSIA (7.6% of people) and Avonex (7.8% of people).

This progression was confirmed after 3 months with predefined increases in Expanded Disability Status Scale scores.

*Avonex® (interferon beta-1a).
†Results included patients from multiple studies, continued until February 2022.

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ZEPOSIA (ozanimod) 0.92 mg capsules

ZEPOSIA & the brain

Important cognitive aspects of MS were measured during the clinical studies after the studies were complete (in what's called a "post-study analysis"). The results for ZEPOSIA® (ozanimod) were measured versus a leading injectable medicine, Avonex® (interferon beta-1a).

Based on the way these studies were designed, the difference between people who took ZEPOSIA and those who took Avonex was not considered statistically significant. Because **there was no significant difference in these results**, it can't be determined by this study whether the following results were due to treatment with ZEPOSIA or if they happened by chance.

Measuring brain volume loss

Everyone loses brain volume as they age, but for people with MS, it can happen more quickly. In both clinical studies, the change in the volume of the whole brain (white matter and grey matter) was measured, as well as grey matter alone.

- **White matter** is where signals pass from one part of the brain to another (and to the rest of the body)
- **Grey matter is found on the surface of the brain and deep within it.** These are areas where communication signals begin

Cognitive processing speed was also measured

Cognitive processing speed is a way to show how quickly the brain is able to receive information, process it correctly, and react to it. **Changes in speed were measured in the 1-year study as part of the Multiple Sclerosis Functional Composite (MSFC)**, a common evaluation for people with MS, which is made up of 3 tests:

- **The Symbol Digit Modalities Test (SDMT)**, which evaluates a person's ability to review, assess, and process information, and then perform a task based on that assessment
- The 2 other tests include **the 9-hole peg test** and **the timed 25-foot walk**

ZEPOSIA (ozanimod) 0.92 mg capsules

MEASURING BRAIN VOLUME & GREY MATTER LOSS* (2-YEAR STUDY)

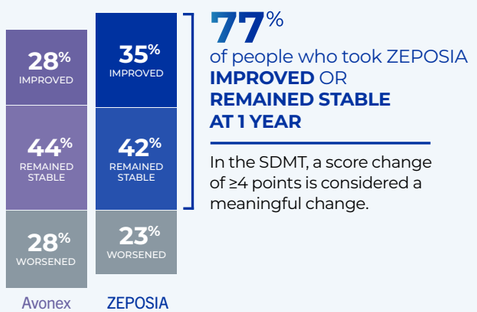
↓26%
REDUCTION in BRAIN VOLUME LOSS
vs Avonex†
(ZEPOSIA loss was 0.71% vs 0.94% for a leading injectable)

↓60%
REDUCTION in SURFACE GREY MATTER LOSS
vs Avonex‡
(ZEPOSIA loss was 0.44% vs 1.11% for a leading injectable)

↓27%
REDUCTION in DEEP GREY MATTER LOSS
vs Avonex§
(ZEPOSIA loss was 1.40% vs 1.85% for a leading injectable)

MEASURING COGNITIVE PROCESSING SPEED (POST 1-YEAR STUDY)

The SDMT (explained on the previous page) was evaluated on its own after the 1-year clinical study for ZEPOSIA was complete.



77%
of people who took ZEPOSIA **IMPROVED** OR **REMAINED STABLE AT 1 YEAR**

In the SDMT, a score change of ≥4 points is considered a meaningful change.

1-year study: 792 people studied (ZEPOSIA 397, Avonex 395)

Because the evaluations of brain volume loss and cognitive processing speed were not statistically significant, no conclusion should be drawn from the data.

*Measured as an average percentage change.
†2-year study: 787 people studied (ZEPOSIA 390, a leading injectable 397).
‡2-year study: 772 people studied (ZEPOSIA 382, a leading injectable 390).
§2-year study: 776 people studied (ZEPOSIA 385, a leading injectable 391).

Please see full Prescribing Information, including Medication Guide.

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What is ZEPOSIA?

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Adults with moderately to severely active ulcerative colitis (UC)

What are the serious side effects of ZEPOSIA?

ZEPOSIA may cause serious side effects. A serious side effect is a side effect that can sometimes become life threatening and can lead to hospitalization or death.

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- Infections
- Progressive multifocal leukoencephalopathy (PML)
- Slow heart rate (also known as bradyarrhythmia)
- Liver problems
- Increased blood pressure
- Breathing problems
- Macular edema
- Types of skin cancer
- Swelling and narrowing of blood vessels in your brain

If you take or have previously taken ZEPOSIA for multiple sclerosis (MS):

You may have severe worsening of MS symptoms after stopping ZEPOSIA. Your symptoms of MS may return and become worse compared to before or during treatment.

What are the most common side effects?

The most common side effects of ZEPOSIA can include:

- Upper respiratory tract infection
- Elevated liver enzymes
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- Back pain
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- Headache

These are not all of the possible side effects of ZEPOSIA.

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Please see additional Important Safety Information on pages 16–22.

ZEPOSIA (ozanimod) 0.92 mg capsules

Understanding safety and side effects

During the 1-year and 2-year clinical studies, the safety and side effects of ZEPOSIA® (ozanimod) were evaluated in 882 people.

90% of people taking ZEPOSIA **REMAINED ON TREATMENT** throughout the clinical studies

Of those who stopped taking ZEPOSIA, 3% did so because of a side effect they experienced. The rest left the studies for a variety of other reasons.

ZEPOSIA may cause serious side effects

The serious side effects of ZEPOSIA may include:

- **Infections:** ZEPOSIA can increase your risk of serious infections that can be life-threatening and cause death. Symptoms include fever, feeling very tired, flu-like symptoms, cough, painful and frequent urination (signs of a urinary tract infection), rash, or symptoms of meningitis, such as headache with fever, neck stiffness, sensitivity to light, nausea, or confusion
- **Progressive multifocal leukoencephalopathy (PML):** ZEPOSIA can increase your risk for PML, which is a rare brain infection that gets worse over days to weeks, and usually leads to death or severe disability
- **ZEPOSIA may cause your heart rate to temporarily slow down (also known as bradyarrhythmia) when you start taking ZEPOSIA** — especially during the first 8 days. Symptoms include dizziness, lightheadedness, feeling like your heart is beating slowly or skipping beats, shortness of breath, confusion, chest pain, or tiredness
- **Liver problems:** Symptoms include unexplained nausea, vomiting, stomach area (abdominal) pain, tiredness, loss of appetite, yellowing of the whites of your eyes or skin, or dark-colored urine

These are not all of the possible serious side effects of ZEPOSIA. Please see full Prescribing Information inside back pocket for all of the side effects reported by those taking ZEPOSIA. If you experience any side effects while taking ZEPOSIA, be sure to talk to your doctor right away.

ZEPOSIA (ozanimod) 0.92 mg capsules

The ZEPOSIA experience

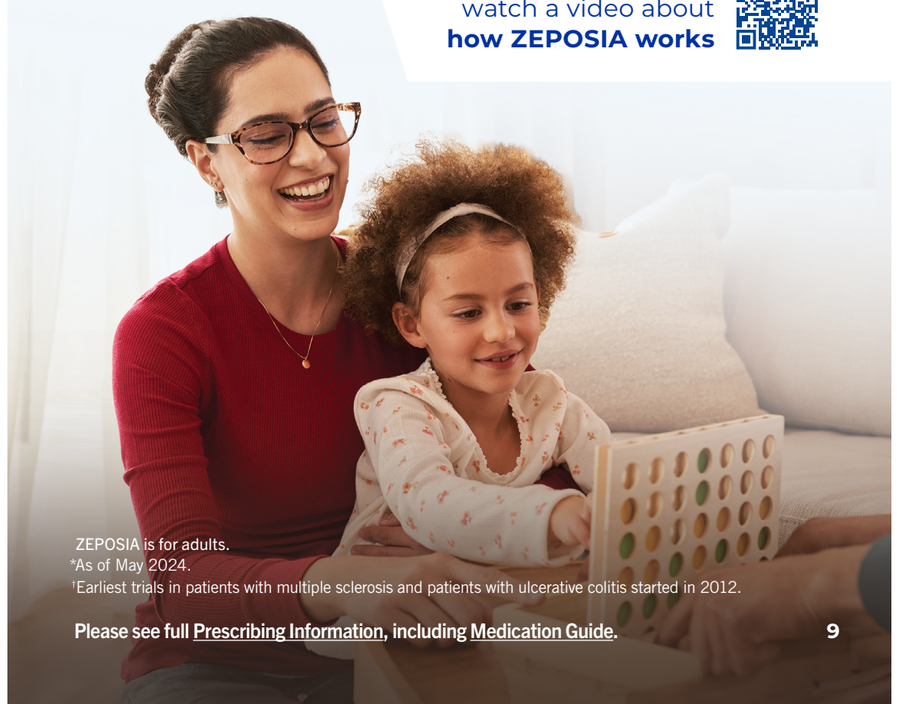
How many people have received ZEPOSIA?

Since approval,
~52,000 patients have received ZEPOSIA
across 2 conditions—multiple sclerosis and ulcerative colitis*

How long has ZEPOSIA been studied?

ZEPOSIA has been studied for nearly 10 years
across 6 clinical trials† in both conditions

Scan this code to watch a video about **how ZEPOSIA works**



ZEPOSIA is for adults.
*As of May 2024.
†Earliest trials in patients with multiple sclerosis and patients with ulcerative colitis started in 2012.

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ZEPOSIA (ozanimod) 0.92 mg capsules

Getting started with ZEPOSIA

If your MS healthcare team has decided that you are an appropriate patient for ZEPOSIA® (ozanimod), a ZEPOSIA start form (prescription) will be submitted for you. **What comes next is explained below.**

Support from the start

A Support Coordinator from the ZEPOSIA 360 Support™ program will call to guide you through the support offerings available, such as **help navigating your insurance benefits* and all of the possible savings options** (see page 13).

Always know when a Support Coordinator is calling by saving this number to your phone: **1-833-ZEPOSIA** (833-937-6742).

Scan this code to save the Support Coordinator number to your phone contacts—and **be sure to answer the call**

*The accurate completion of reimbursement- or coverage-related documentation is the responsibility of the healthcare provider and patient. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement for any services or item.

ZEPOSIA (ozanimod) 0.92 mg capsules

Screening support

Before you start taking ZEPOSIA, your doctor will request a few routine tests.

Before starting ZEPOSIA

Electrocardiogram (ECG)—a common test that monitors your heart and makes sure it’s working normally before you start treatment

Blood work—including complete blood count and liver function test

Near the start of your treatment

Eye and skin exam—recommended to monitor any potential changes while taking ZEPOSIA

Be sure to review your list of current or prior medication, vitamins, herbal supplements, and vaccination records to ensure immunizations are up to date with current guidelines.

See more on next page >

Please see full Prescribing Information, including Medication Guide.

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ZEPOSIA (ozanimod) 0.92 mg capsules

Getting started with ZEPOSIA
(continued)

Start taking ZEPOSIA

Once you're approved to begin treatment, the ZEPOSIA® (ozanimod) Starter Kit will be provided by your healthcare team or delivered directly to your home.

The ZEPOSIA Starter Kit has 2 parts:

1. **A 7-day Starter Pack** for your first week of treatment. The pills in this pack help increase your dosage of ZEPOSIA gradually. Each pill is labeled with the day and dosage. Be sure to follow the instructions written on the pack and take the pills in the correct order
2. **The regular dosage of ZEPOSIA** (orange capsules) you'll begin taking on day 8 (after completing the 7-day Starter Pack)

Ways to save

ZEPOSIA is covered for over 90% of people with private or commercial insurance.* But with the ZEPOSIA 360 Support™ program, there are still ways to save.

- **A co-pay offer** that may help those who are eligible and commercially insured pay **as little as $0 a month for ZEPOSIA**
- **Reimbursement for medical costs** associated with appointments or routine tests before starting ZEPOSIA, for eligible, commercially insured patients†
- **The ZEPOSIA Bridge Program** may provide help for eligible, commercially insured patients who are experiencing a delay in obtaining coverage or have been denied coverage†

*Data provided by Bristol Myers Squibb and is current as of March 2024.
†See full Terms and Conditions on pages 14 and 15.

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ZEPOSIA 360 Support™ Terms & Conditions

The 360 Support program offers several different ways for eligible patients to save on costs when starting treatment—and help make sure they receive ZEPOSIA® (ozanimod) even if delays in insurance coverage occur. Here are the full terms & conditions for each program.

Combined Co-pay Programs (Drug and Medical Benefit)

ZEPOSIA Co-pay Program is valid only for patients with commercial insurance. The Program includes a prescription benefit offer for out-of-pocket drug costs and a medical assessment benefit offer for out-of-pocket costs for the initial blood tests, ECG screening, skin exam, and eye exam where the full cost is not covered by patient's insurance. Patients are not eligible for the prescription benefit offer if they have prescription insurance coverage through a state or federal healthcare program, including but not limited to Medicare, Medicaid, Medigap, CHAMPVA, TRICARE, Veterans Affairs (VA), or Department of Defense (DoD) programs. Patients are not eligible for the medical assessment benefit offer if they have insurance coverage for their prescription or medical assessment through a state or federal healthcare program, or reside in Massachusetts, Minnesota or Rhode Island. Patients who move from commercial plans to state or federal healthcare programs will no longer be eligible. Patient must be 18 years of age or older. Eligible patients with an activated co-pay card and a valid prescription may pay as little as $0 per 30-day supply; monthly, annual, and/or per-claim maximum program benefits may apply and vary from patient to patient, depending on the terms of a patient's prescription drug plan and to ensure that the funds are used for the benefit of the patient, based on factors determined solely by Bristol-Myers Squibb. Some prescription drug plans have established programs referred to as "co-pay maximizer" programs. A co-pay maximizer program is one in which the amount of the patient's out-of-pocket costs is adjusted to reflect the availability of support offered by a co-pay support program. Patients enrolled in co-pay maximizer programs may receive program benefits that vary over time to ensure the program funds are used for the benefit of the patient. Patients will be evaluated for ongoing eligibility in the prescription copay program to continue enrollment in the program. In the event patients experience a change in insurance coverage or BMS makes changes to the copay assistance program, patients may be required to re-enroll into the program and provide updated insurance information to determine eligibility. Eligible commercially insured patients may pay as little as $0 in out-of-pocket costs for the medical assessment, subject to a maximum benefit of $2,000. The medical benefit offer only applies to clinical baseline assessment services covered by the Program. Patients are responsible for any costs that exceed the maximum amounts. To receive the medical assessment benefit, an Explanation of Benefits (EOB) form must be submitted, along with copies of receipts for any payments made. All Program payments are for the benefit of the patient only. Patients, pharmacists, and prescribers may not seek reimbursement from health insurance, health savings or flexible spending accounts, or any third party, for any part of the prescription or medical assessment benefit received by the patient through this Program. Patient's acceptance of any Program benefit confirms that it is consistent with patient's insurance and that patient will report the value received as may be required by his/her insurance provider. Program valid only in the United States and Puerto Rico. Void where prohibited by law, taxed, or restricted. The Program cannot be combined with any other offer, rebate, coupon, or free trial. The Program is not conditioned on any past, present or future purchase, including refills. The Program is not insurance. Other limitations may apply. Bristol Myers Squibb reserves the right to rescind, revoke, or amend this Program at any time without notice.

ZEPOSIA Free Trial Offer/Starter Kit

Patient must have a valid prescription for ZEPOSIA for an FDA-approved indication. Patient must be new to therapy and have not previously received a sample or filled a prescription for ZEPOSIA. Patient is responsible for applicable taxes, if any. This offer is limited to one use per patient per lifetime and is non-transferable. Cannot be combined with any other rebate/coupon, free trial, or similar offer. No substitutions permitted. Patients, pharmacists, and prescribers cannot seek reimbursement for the ZEPOSIA Free Trial/Starter Kit from health insurance or any third party, including state or federally funded programs. Patients may not count the ZEPOSIA Free Trial/Starter Kit as an expense incurred for purposes of determining out-of-pocket costs for any plan, including Medicare Part D true out-of-pocket costs (TrOOP). Offer is not conditioned on any past, present, or future purchase, including refills. Only valid in the United States and US Territories. Void where prohibited by law or restricted. The program is not insurance. Bristol Myers Squibb reserves the right to rescind, revoke, or amend this offer at any time without notice.

ZEPOSIA In-Home Medical Services Program

Patient must have a valid prescription for ZEPOSIA for an FDA-approved indication. Patients are not eligible if they have prescription insurance coverage through a state or federal healthcare program, including but not limited to Medicare, Medicaid, Medigap, CHAMPVA, TRICARE, Veterans Affairs (VA), or Department of Defense (DoD) programs, or reside in Rhode Island. To receive the In-Home Medical Services Program, the prescriber must request in-home assessment assistance through the ZEPOSIA 360 Support program. The patient's insurance will not be billed, and the patient will not be responsible for any out-of-pocket costs. Patients who move from commercial plans to state or federal healthcare programs will no longer be eligible. The program cannot be combined with any other offer, rebate, coupon, or free trial. The program is not conditioned on any past, present, or future purchase, including refills. Only valid in the United States and US Territories. Void where prohibited by law, taxed, or restricted. The program is not insurance. Bristol-Myers Squibb Company reserves the right to rescind, revoke, or amend this program at any time without notice. Other limitations may apply.

Bridge Program

The Bridge Program is available at no cost for eligible, commercially insured, on-label diagnosed patients if there is a delay in determining whether commercial prescription coverage is available, and is not contingent on any purchase requirement, for up to 24 months (dispensed in 30-day increments). The Bridge Program is not available to patients who have prescription insurance coverage through a state or federal healthcare program, including but not limited to Medicare, Medicaid, Medigap, CHAMPVA, TRICARE, Veterans Affairs (VA), or Department of Defense (DoD) programs. Appeal of any prior authorization denial must be made within 90 days or as per payer guidelines, to remain in the program. Eligibility will be re-verified in January for patients continuing into the following year, and may be at other times during program participation. Offer is not health insurance. Once coverage is approved by the patient's commercial insurance plan, the patient will no longer be eligible. Void where prohibited by law, taxed, or restricted. Bristol-Myers Squibb Company reserves the right to rescind, revoke, or amend this program at any time without notice. Other limitations may apply.

Please see full Prescribing Information, including Medication Guide.

What is the most important information I should know about ZEPOSIA?

This is a summary of important information that you need to know about ZEPOSIA. Your healthcare provider can work with you to help answer any questions you may have about this medication. Keep this information in a safe place, so you can refer to it before and during your treatment.

What is ZEPOSIA?

ZEPOSIA is a prescription medicine used to treat:

Adults with relapsing forms of multiple sclerosis (MS), including:

- **C**linically **I**solated **S**yndrome (**CIS**),
- **R**elapsing-**R**emitting **MS** Disease (**RRMS**), and
- Active **S**econdary **P**rogressive **MS** Disease (**SPMS**)

Adults with moderately to severely active ulcerative colitis (UC)

What are the serious side effects of ZEPOSIA?

ZEPOSIA may cause serious side effects. A serious side effect is a side effect that can sometimes become life threatening and can lead to hospitalization or death.

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including:

- Infections
- Progressive multifocal leukoencephalopathy (PML)
- Slow heart rate (also known as bradyarrhythmia)
- Liver problems
- Increased blood pressure
- Breathing problems
- Macular edema
- Types of skin cancer
- Swelling and narrowing of blood vessels in your brain

If you take or have previously taken ZEPOSIA for multiple sclerosis (MS):

You may have severe worsening of MS symptoms after stopping ZEPOSIA. Your symptoms of MS may return and become worse compared to before or during treatment.

What are the most common side effects?

The most common side effects of ZEPOSIA can include:

- Upper respiratory tract infection
- Elevated liver enzymes
- Sudden drops in blood pressure when you stand up (orthostatic hypotension)
- Painful and frequent urination
- Back pain
- High blood pressure
- Headache

These are not all of the possible side effects of ZEPOSIA.

Talk to your healthcare provider for more information or advice about side effects. You are encouraged to report side effects of prescription drugs to the FDA by visiting www.fda.gov/medwatch or calling 1-800-FDA-1088.

Please see additional Important Safety Information on pages 16–22.

ZEPOSIA (ozanimod) 0.92 mg capsules

Important facts about ZEPOSIA

This is a summary of important information that you need to know about ZEPOSIA. Your healthcare provider can work with you to help answer any questions you may have about this medication. Keep this information in a safe place, so you can refer to it before and during your treatment.

Look out for the following icons as you read:

Talk to your healthcare provider

Call a healthcare provider right away

Helpful information to remember

What is ZEPOSIA?

ZEPOSIA® (ozanimod) is a prescription medicine used to treat:

Adults with relapsing forms of multiple sclerosis (MS), including:

- **C**linically **I**solated **S**yndrome (**CIS**),
- **R**elapsing-**R**emitting **MS** Disease (**RRMS**), and
- Active **S**econdary **P**rogressive **MS** Disease (**SPMS**)

Adults with moderately to severely active ulcerative colitis (UC)

It is not known if ZEPOSIA is safe and effective in children under 18 years of age.

ZEPOSIA should not be taken if:

- You have or have had problems with your heart or blood flow such as:
  - A heart attack, chest pain (unstable angina), a stroke or mini-stroke (transient ischemic attack [TIA]), or certain types of heart failure in the last six months
  - A history of certain types of irregular or abnormal heartbeat (arrhythmia) that is not corrected by a pacemaker
- You have untreated, severe breathing problems during your sleep (sleep apnea)
- You take certain medicines called monoamine oxidase (MAO) inhibitors (such as selegiline, phenelzine, linezolid)

Talk to your healthcare provider before taking ZEPOSIA if you have any of these conditions, or don't know if you have any of these conditions.

What is the most important information I should know about ZEPOSIA?

ZEPOSIA may cause serious side effects. A serious side effect is a side effect that can sometimes become life threatening and can lead to hospitalization or death. The serious side effects of ZEPOSIA may include:

Infections. ZEPOSIA can increase your risk of serious infections that can be life-threatening and cause death. ZEPOSIA lowers the number of white blood cells (lymphocytes) in your blood. Having fewer white blood cells weakens your immune system, and increases your risk of serious infections. Before starting ZEPOSIA, your healthcare provider may do a blood test to make sure that your white blood cells are not too low. After stopping ZEPOSIA, the number of white blood cells that you have in your blood usually goes back to normal within three months.

Call your healthcare provider right away if you have any of the following symptoms of an infection during treatment with ZEPOSIA, and for three months after your last dose of ZEPOSIA:

- Fever
- Feeling very tired
- Flu-like symptoms
- Cough
- Painful and frequent urination (signs of a urinary tract infection)
- Rash
- Headache with fever, neck stiffness, sensitivity to light, nausea, or confusion (these may be symptoms of meningitis, an infection of the lining around your brain and spine)

Your healthcare provider may delay starting, or may stop your ZEPOSIA treatment if you have an infection.

Progressive multifocal leukoencephalopathy (PML). PML is a rare brain infection that usually leads to death or severe disability. ZEPOSIA can increase your risk for PML. PML usually happens in people with weakened immune systems but has happened in people who do not have weakened immune systems.

Call your healthcare provider right away if you have any new or worsening symptoms of PML that have lasted several days. Symptoms get worse over days to weeks. These symptoms include:

- Weakness on one side of your body
- Loss of coordination in your arms or legs
- Decreased strength
- Balance problems
- Changes in your vision
- Changes in thinking or memory
- Confusion
- Changes in your personality

Your healthcare provider will stop treatment with ZEPOSIA if you are showing symptoms of PML.

Slow heart rate (also known as bradyarrhythmia) when you start taking ZEPOSIA. ZEPOSIA may cause your heart rate to slow down temporarily, especially during the first eight days that you start taking it. Before starting ZEPOSIA, your healthcare provider will do a test called an electrocardiogram (ECG) to measure the electrical activity of your heart.

Call your healthcare provider if you have any of these symptoms:

- Feeling dizzy
- Feeling lightheaded
- Feeling tired
- Feeling like your heart is beating slowly or skipping beats
- Shortness of breath
- Feeling confused
- Chest pain

Your healthcare provider will increase your dosage slowly to reduce the risk of slow heart rate. It is important that you follow directions from your healthcare provider when starting ZEPOSIA and if you miss a dose. Please see additional information on taking ZEPOSIA below.

Liver problems. ZEPOSIA may cause liver damage. Your healthcare provider will do blood tests to check your liver's health before you start taking ZEPOSIA and periodically during treatment.

Call your healthcare provider right away if you have any of these symptoms of liver problems:

- Unexplained nausea
- Vomiting
- Dark colored urine
- Pain in the stomach (abdominal) area
- Feeling tired
- Loss of appetite
- Yellowing of the whites of your eyes or skin

What is the most important information I should know about ZEPOSIA?

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What is ZEPOSIA?

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Adults with moderately to severely active ulcerative colitis (UC)

What are the serious side effects of ZEPOSIA?

ZEPOSIA may cause serious side effects. A serious side effect is a side effect that can sometimes become life threatening and can lead to hospitalization or death.

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including:

- Infections
- Progressive multifocal leukoencephalopathy (PML)
- Slow heart rate (also known as bradyarrhythmia)
- Liver problems
- Increased blood pressure
- Breathing problems
- Macular edema
- Types of skin cancer
- Swelling and narrowing of blood vessels in your brain

If you take or have previously taken ZEPOSIA for multiple sclerosis (MS):

You may have severe worsening of MS symptoms after stopping ZEPOSIA. Your symptoms of MS may return and become worse compared to before or during treatment.

What are the most common side effects?

The most common side effects of ZEPOSIA can include:

- Upper respiratory tract infection
- Elevated liver enzymes
- Sudden drops in blood pressure when you stand up (orthostatic hypotension)
- Painful and frequent urination
- Back pain
- High blood pressure
- Headache

These are not all of the possible side effects of ZEPOSIA.

Talk to your healthcare provider for more information or advice about side effects. You are encouraged to report side effects of prescription drugs to the FDA by visiting www.fda.gov/medwatch or calling 1-800-FDA-1088.

Important facts about ZEPOSIA (cont'd)

Increased blood pressure. ZEPOSIA can cause your blood pressure to go up. Your healthcare provider should check your blood pressure while you take ZEPOSIA.

Breathing problems. Some people who take ZEPOSIA feel as though they cannot catch their breath (shortness of breath).

Call your healthcare provider right away if you have new or worsening breathing problems.

A problem with your vision called macular edema. ZEPOSIA may cause swelling in the back of the eye (macula). Macular edema can cause some of the same vision symptoms as an MS attack (optic neuritis). You may not notice any symptoms with macular edema. Your healthcare provider should test your vision around the time you start taking ZEPOSIA, periodically while you continue taking ZEPOSIA, and at any time you notice vision changes during treatment with ZEPOSIA. Your chance of developing macular edema is higher if you have diabetes or have had uveitis (a type of inflammation of your eye).

Call your healthcare provider right away if you have any of these symptoms:

- A blind spot, blurriness, or shadows in the center of your vision
- Sensitivity to light
- Unusually colored vision

Types of skin cancer, including basal cell carcinoma, melanoma, and squamous cell carcinoma. Tell your healthcare provider if you have any changes in your skin, including changes in a mole, a new darkened area on your skin, a sore that does not heal, or growths on your skin, such as a bump that may be shiny, pearly white, skin-colored, or pink. Your doctor should check your skin for any changes at the start of and during treatment with ZEPOSIA. Limit the amount of time you spend in sunlight and ultraviolet (UV) light. Wear protective clothing and use a sunscreen with a high sun protection factor.

Swelling and narrowing of blood vessels in your brain. A condition called **P**osterior **R**eversible **E**ncephalopathy **S**yndrome (**PRES**) is a rare condition of ZEPOSIA and other drugs like it. If left untreated, it may lead to a stroke. The symptoms of PRES usually get better once you stop taking ZEPOSIA.

Call your healthcare provider right away if you have any of these symptoms:

- Sudden severe headache
- Sudden confusion
- Sudden changes in or loss of vision
- Seizure

Your healthcare provider will do a test if you have any symptoms of PRES.

If you take or have previously taken ZEPOSIA for multiple sclerosis (MS): You may have severe worsening of MS symptoms after stopping ZEPOSIA. Your symptoms of MS may return and become worse compared to before or during treatment.

Talk to your healthcare provider before you stop taking ZEPOSIA for any reason. Tell your healthcare provider if you have worsening symptoms of MS after stopping ZEPOSIA.

ZEPOSIA (ozanimod) 0.92 mg capsules

What are the most common side effects of ZEPOSIA?

The most common side effects of ZEPOSIA can include:

- Colds or infections that affect the nose, throat, and sinuses (upper respiratory tract infection)
- Elevated liver enzymes
- Sudden drops in blood pressure when you stand up (orthostatic hypotension), which can feel like dizziness or lightheadedness
- Painful and frequent urination (signs of urinary tract infection)
- Back pain
- High blood pressure
- Headache

These are not all of the possible side effects of ZEPOSIA.

Talk to your healthcare provider for more information or advice about side effects. You are encouraged to report side effects of prescription drugs to the FDA by visiting www.fda.gov/medwatch or calling 1-800-FDA-1088.

What should I discuss with my healthcare provider before receiving ZEPOSIA?

Talk to your healthcare provider about all of your medical conditions, including if you have:

- A recent fever or infection
- A disease that makes you unable to fight infections
- Problems with your heart, which may include:
  - A slow heart rate
  - An irregular or abnormal heartbeat (arrhythmia)
  - Heart attack, or chest pain
- High blood pressure
- A history of stroke
- Liver problems
- Breathing problems, while awake or sleeping
- Eye problems, especially eye inflammation (called uveitis)
- Skin cancer (currently or in the past), including basal cell carcinoma (BCC), melanoma, or squamous cell carcinoma (SCC)
- Diabetes

Talk to your healthcare provider if you have had chickenpox, or have received the vaccine for chickenpox.

Your healthcare provider may do a blood test for the chickenpox virus. You may need to get the full course of the chickenpox (Varicella Zoster Virus) vaccine, and then wait one month before you start taking ZEPOSIA.

Talk to your healthcare provider about all the medicines you are taking or have recently taken, including:

- Prescription medicines
- Over-the-counter medicines
- Vitamins
- Herbal supplements

What is the most important information I should know about ZEPOSIA?

This is a summary of important information that you need to know about ZEPOSIA. Your healthcare provider can work with you to help answer any questions you may have about this medication. Keep this information in a safe place, so you can refer to it before and during your treatment.

What is ZEPOSIA?

ZEPOSIA is a prescription medicine used to treat:

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Adults with moderately to severely active ulcerative colitis (UC)

What are the serious side effects of ZEPOSIA?

ZEPOSIA may cause serious side effects. A serious side effect is a side effect that can sometimes become life threatening and can lead to hospitalization or death.

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including:

- Infections
- Progressive multifocal leukoencephalopathy (PML)
- Slow heart rate (also known as bradyarrhythmia)
- Liver problems
- Increased blood pressure
- Breathing problems
- Macular edema
- Types of skin cancer
- Swelling and narrowing of blood vessels in your brain

If you take or have previously taken ZEPOSIA for multiple sclerosis (MS):

You may have severe worsening of MS symptoms after stopping ZEPOSIA. Your symptoms of MS may return and become worse compared to before or during treatment.

What are the most common side effects?

The most common side effects of ZEPOSIA can include:

- Upper respiratory tract infection
- Elevated liver enzymes
- Sudden drops in blood pressure when you stand up (orthostatic hypotension)
- Painful and frequent urination
- Back pain
- High blood pressure
- Headache

These are not all of the possible side effects of ZEPOSIA.

Talk to your healthcare provider for more information or advice about side effects. You are encouraged to report side effects of prescription drugs to the FDA by visiting www.fda.gov/medwatch or calling 1-800-FDA-1088.

Please see additional Important Safety Information on pages 16–22.

ZEPOSIA (ozanimod) 0.92 mg capsules

Important facts about ZEPOSIA (cont'd)

It is especially important to tell your healthcare provider if you take, or have taken any medicines that:

- Affect or lower your immune system (such as alemtuzumab)
- Control your heart rhythm (such as antiarrhythmics) or heartbeat
- Promote or inhibit CYP2C8 activity (such as rifampin or gemfibrozil)
- Are opioids
- Treat depression
- Treat Parkinson's disease
- Control your heart rate and blood pressure (such as beta blocker and calcium channel blocker medicines)
- Are medicines called monoamine oxidase (MAO) inhibitors (such as selegiline, phenelzine, or linezolid)

Talk to your healthcare provider if you are not sure if you take any of these medications. Using ZEPOSIA with other medicines can cause serious side effects. Keep a list of the medicines you take to show your healthcare provider and pharmacist.

Talk to your healthcare provider if you have received a vaccine in the past 30 days, or are scheduled to receive a vaccine (immunization). ZEPOSIA may cause vaccines to be less effective.

You should not receive **live** vaccines during treatment with ZEPOSIA, for at least one month before taking ZEPOSIA, and for three months after you stop taking ZEPOSIA. Live vaccines are vaccines that use a small amount of the weakened virus. Some common live vaccines (among others) include:

- Measles, mumps, and rubella (MMR)
- Intranasal flu vaccine
- Rotavirus
- Smallpox
- Chickenpox
- Yellow fever

What should I discuss with my healthcare provider about pregnancy, birth control, and breastfeeding?

Talk to your healthcare provider if:

You are pregnant or plan to become pregnant – ZEPOSIA may harm your unborn baby. If you are able to become pregnant, you should use effective birth control during your treatment with ZEPOSIA and for three months after you stop taking ZEPOSIA.

Talk to your healthcare provider about birth control methods you can use with ZEPOSIA.

You are breastfeeding or plan to breastfeed – It is not known if ZEPOSIA passes into your breast milk.

Talk to your healthcare provider about the best way to feed your baby if you take ZEPOSIA.

ZEPOSIA (ozanimod) 0.92 mg capsules

Call your healthcare provider right away if you become pregnant or think you are pregnant while taking ZEPOSIA, or within three months after you stop taking it.

If you are taking ZEPOSIA for multiple sclerosis: Talk to your healthcare provider about registering for the ZEPOSIA Pregnancy Registry. This registry is for people with multiple sclerosis who become pregnant during treatment with ZEPOSIA. Its purpose is to collect information about you and your baby's health. Either you or your healthcare provider can enroll you in this registry by calling **1-877-301-9314** or visiting **www.zeposiapregnancyregistry.com**.

How will I take ZEPOSIA?

Take ZEPOSIA exactly as your healthcare provider tells you. Your healthcare provider may change your dose schedule (frequency) if certain liver problems exist.

ZEPOSIA is an opaque capsule filled with a white to off-white powder. It comes in three dosage strengths (0.23 mg, 0.46 mg, and 0.92 mg) that are different colors. The capsules all have "OZA" and their dosage strength in mg printed in black ink.

Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, and microcrystalline cellulose

Capsule shell inactive ingredients: black iron oxide, gelatin, red iron oxide, titanium oxide, and yellow iron oxide

- ✓ **Do** swallow ZEPOSIA capsules whole
- ✓ **Do** take ZEPOSIA with or without food
- ✓ **Do** take ZEPOSIA exactly as your healthcare provider tells you
- ✗ **Do not** skip a dose of ZEPOSIA
- ✗ **Do not** stop taking ZEPOSIA without talking with your healthcare provider first

What is the most important information I should know about ZEPOSIA?

This is a summary of important information that you need to know about ZEPOSIA. Your healthcare provider can work with you to help answer any questions you may have about this medication. Keep this information in a safe place, so you can refer to it before and during your treatment.

What is ZEPOSIA?

ZEPOSIA is a prescription medicine used to treat:

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- Active **S**econdary **P**rogressive **MS** Disease (**SPMS**)

Adults with moderately to severely active ulcerative colitis (UC)

What are the serious side effects of ZEPOSIA?

ZEPOSIA may cause serious side effects. A serious side effect is a side effect that can sometimes become life threatening and can lead to hospitalization or death.

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including:

- Infections
- Progressive multifocal leukoencephalopathy (PML)
- Slow heart rate (also known as bradyarrhythmia)
- Liver problems
- Increased blood pressure
- Breathing problems
- Macular edema
- Types of skin cancer
- Swelling and narrowing of blood vessels in your brain

If you take or have previously taken ZEPOSIA for multiple sclerosis (MS):

You may have severe worsening of MS symptoms after stopping ZEPOSIA. Your symptoms of MS may return and become worse compared to before or during treatment.

What are the most common side effects?

The most common side effects of ZEPOSIA can include:

- Upper respiratory tract infection
- Elevated liver enzymes
- Sudden drops in blood pressure when you stand up (orthostatic hypotension)
- Painful and frequent urination
- Back pain
- High blood pressure
- Headache

These are not all of the possible side effects of ZEPOSIA.

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Please see additional Important Safety Information on pages 16–22.

ZEPOSIA (ozanimod) 0.92 mg capsules

Important facts about ZEPOSIA (cont'd)

Starting ZEPOSIA (days 1 to 7): Your treatment with ZEPOSIA begins with a 7-day Starter Pack. This pack includes all of the pills that you need for the first 7 days of treatment, and helps to gradually increase your dosage of ZEPOSIA. Be sure to follow the instructions written on the pack and take the pills in the correct order.

Days 1 – 4 

One **0.23 mg capsule** one time per day
This capsule is light grey

Days 5 – 7 

One **0.46 mg capsule** one time per day
This capsule is half-light grey and half-orange

Continuing ZEPOSIA (days 8 onwards): After finishing your first week of treatment, you will take your regular dose of ZEPOSIA.

Days 8 onwards 

One **0.92 mg capsule** one time per day, or as directed by your healthcare provider
This capsule is orange

What if I miss a dose of ZEPOSIA?

Do not take an extra dose.

During days 1–14 (first two weeks) of starting treatment: If you miss one or more doses, let your healthcare provider know. You will need to restart your ZEPOSIA treatment and get a new 7-day Starter Pack.

After the first 14 days of treatment: If you miss one dose of ZEPOSIA, take one capsule at your next usual time. You can continue your treatment as planned.

How should I store ZEPOSIA?

ZEPOSIA capsules should be stored at **room temperature** between 68°F to 77°F (20°C to 25°C). Keep ZEPOSIA and all medicines out of reach of children.

For more information, please see accompanying U.S. Full Prescribing Information and Medication Guide for ZEPOSIA. Talk to your healthcare provider for more information about this medication.

ZEPOSIA (ozanimod) 0.92 mg capsules

Notes

It can be helpful to record additional notes while talking to your healthcare team.

What is the most important information I should know about ZEPOSIA?

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- Slow heart rate (also known as bradyarrhythmia)
- Liver problems
- Increased blood pressure
- Breathing problems
- Macular edema
- Types of skin cancer
- Swelling and narrowing of blood vessels in your brain

If you take or have previously taken ZEPOSIA for multiple sclerosis (MS):

You may have severe worsening of MS symptoms after stopping ZEPOSIA. Your symptoms of MS may return and become worse compared to before or during treatment.

What are the most common side effects?

The most common side effects of ZEPOSIA can include:

- Upper respiratory tract infection
- Elevated liver enzymes
- Sudden drops in blood pressure when you stand up (orthostatic hypotension)
- Painful and frequent urination
- Back pain
- High blood pressure
- Headache

These are not all of the possible side effects of ZEPOSIA.

Talk to your healthcare provider for more information or advice about side effects. You are encouraged to report side effects of prescription drugs to the FDA by visiting www.fda.gov/medwatch or calling 1-800-FDA-1088.

Please see additional Important Safety Information on pages 16–22.

ZEPOSIA (ozanimod) 0.92 mg capsules

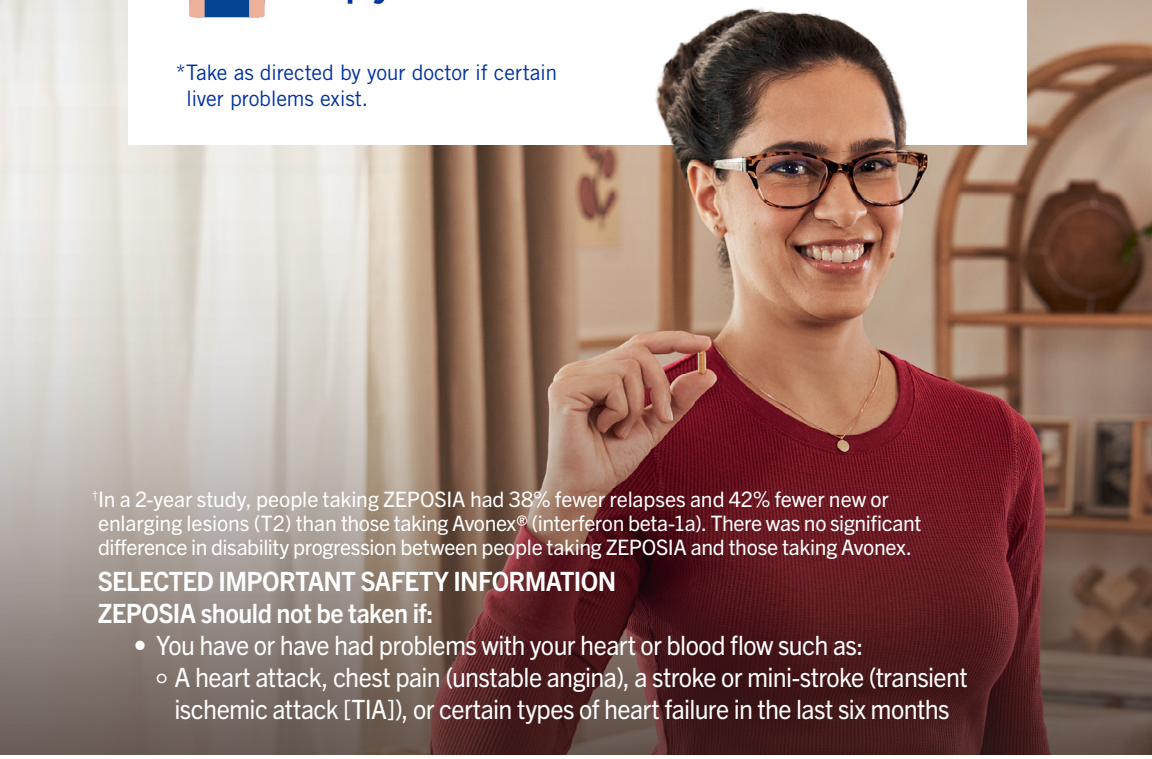
ZEPOSIA® (ozanimod) | 0.92 mg capsules

ZEPOSIA® (ozanimod) is **one pill, once a day*** for relapsing multiple sclerosis

Proven more effective than Avonex® (interferon beta-1a) in preventing relapses and lesions†

The ZEPOSIA 360 Support™ program can **help you save**

*Take as directed by your doctor if certain liver problems exist.



†In a 2-year study, people taking ZEPOSIA had 38% fewer relapses and 42% fewer new or enlarging lesions (T2) than those taking Avonex® (interferon beta-1a). There was no significant difference in disability progression between people taking ZEPOSIA and those taking Avonex.

SELECTED IMPORTANT SAFETY INFORMATION

ZEPOSIA should not be taken if:

- You have or have had problems with your heart or blood flow such as:
  - A heart attack, chest pain (unstable angina), a stroke or mini-stroke (transient ischemic attack [TIA]), or certain types of heart failure in the last six months

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Follow us on Instagram **@ZEPOSIA_ozanimod**

Please see Important Safety Information on pages 16–22 and full Prescribing Information, including Medication Guide.

Bristol Myers Squibb®