

Using this ulcerative colitis treatment guide

This digital guide is intended to help you navigate a conversation with your patients about their ulcerative colitis (UC) and ZEPOSIA® (ozanimod) as a treatment option for moderate to severe UC during telehealth appointments.

Click or tap on the tabs of the navigation menu on the right to go straight to the specific information you'd like to discuss with your patients.

This document also includes QR codes for your patients to further dive into more information about UC and ZEPOSIA.

Choose from the navigation on the right, or [click here](#) to start the presentation.

This page is not intended for patients.

Please see [Important Safety Information](#) at the end of this presentation and full [Prescribing Information](#), including [Medication Guide](#).

Get to know ZEPOSIA® (ozanimod)

ZEPOSIA® (ozanimod) is a prescription medicine used to treat moderately to severely active ulcerative colitis (UC) in adults.

It is not known if ZEPOSIA is safe and effective in children.

Do not take ZEPOSIA if you:

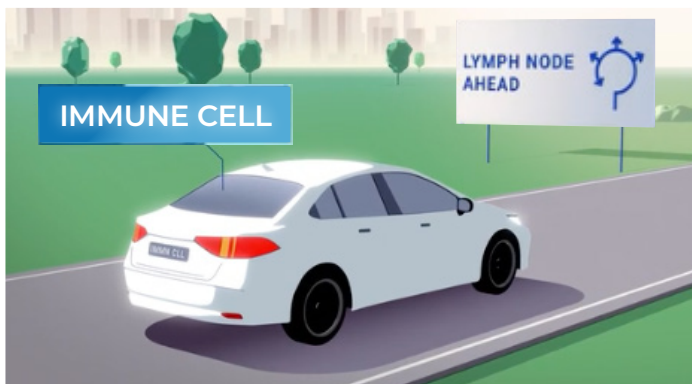
- have had a heart attack, chest pain (unstable angina), stroke or mini-stroke (transient ischemic attack or TIA), or certain types of heart failure in the last 6 months
- have or have had a history of certain types of an irregular or abnormal heartbeat (arrhythmia) that is not corrected by a pacemaker
- have untreated, severe breathing problems during your sleep (sleep apnea)
- take certain medicines called monoamine oxidase (MOA) inhibitors (such as selegiline, phenelzine, linezolid)

Talk to your healthcare provider before taking ZEPOSIA if you have any of these conditions or do not know if you have any of these conditions.

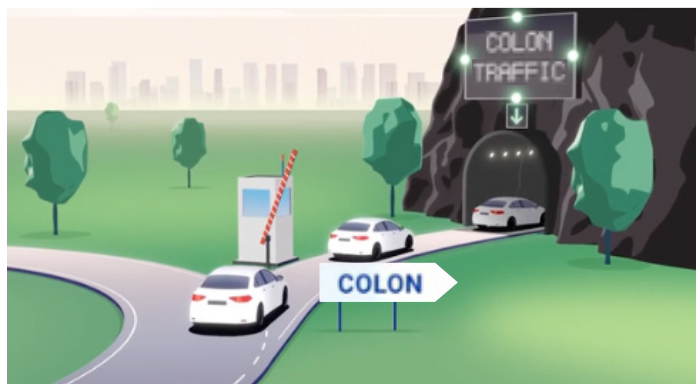
Ulcerative colitis (UC) is a type of inflammatory bowel disease (IBD) that causes inflammation in the lining of the colon. It is not fully known what causes UC, but it is thought to be related to an irregular immune response.

Because some treatments are thought to work within the immune system, it is important to understand the role the immune system plays in UC

To better understand, it may help to **think of the body as a system of roadways**, and **immune cells as cars**:



When the immune system is functioning normally, **immune cells circulate throughout the body** to where they're needed most. They travel from lymph nodes to fight off problems, such as infections.



In UC, the immune system responds incorrectly by recruiting immune cells to the colon (which is made up of the large intestines and rectum).



This incorrect immune response causes ongoing (chronic) inflammation, **which damages the colon and causes symptoms (like rectal bleeding and increased stool frequency)** and other potential long-term complications.

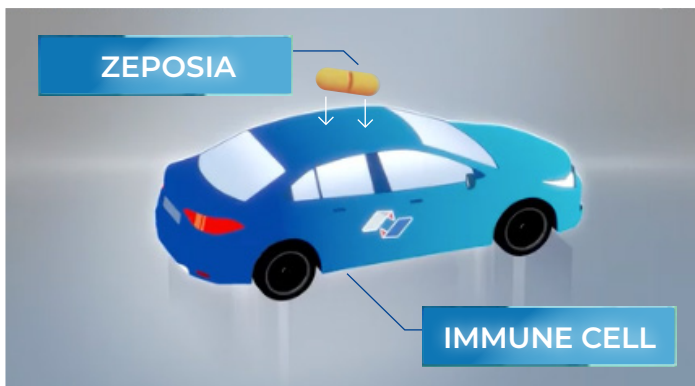
See the next page for how S1P receptor modulators are thought to work

S1P receptor modulators and the immune system

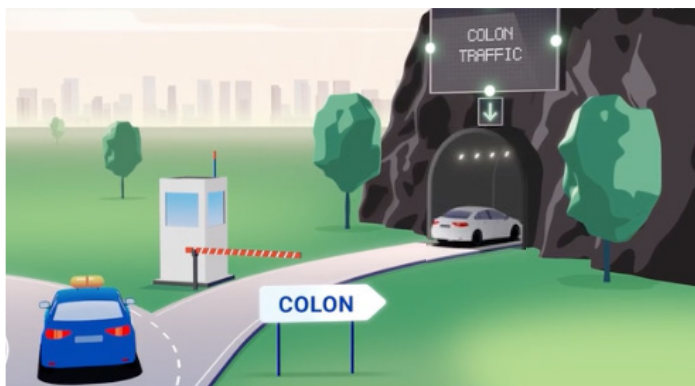
S1P receptor modulators, like ZEPOSIA® (ozanimod), are a type of treatment that are thought to work within the immune system to treat UC.

ZEPOSIA is thought to target a specific part of immune cells (S1P receptors) that play a role in UC inflammation

The exact way ZEPOSIA works isn't fully understood.



ZEPOSIA attaches to S1P receptors, which are on the surface of certain immune cells.



ZEPOSIA acts as a gatekeeper. It sends a signal that prevents these immune cells from leaving the lymph nodes and entering the colon.



Fewer immune cells in your colon may mean a lower risk of damaging inflammation—and the symptoms that come with it.



Scan here or visit ZEPOSIA.com/treatingUC to find out how ZEPOSIA is thought to work.

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5 key facts about ZEPOSIA® (ozanimod)



ZEPOSIA can be next after trying 5-ASAs (pills, enemas, or suppositories)

ZEPOSIA is a once-daily* oral pill—not an injection or infusion. It may be the next step for those who haven’t reached their goal of achieving and maintaining UC remission after trying 5-ASAs (eg, balsalazide, mesalamine, olsalazine, or sulfasalazine).

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



Lasting remission and early symptom relief

In clinical trials, people taking ZEPOSIA experienced lasting remission.† In as early as 2 weeks, some experienced reduced rectal bleeding and fewer trips to the bathroom.

†37% achieved remission at 1 year vs 19% on placebo.



Reduced intestinal inflammation

ZEPOSIA can **help with intestinal healing** by visibly reducing inflammation on and below the surface of the colon lining.‡

‡30% of patients achieved this result at 1 year, compared to 14% on placebo. Impact of intestinal healing on UC progression and long-term outcomes was not studied.



Studied for more than 10 years

ZEPOSIA has been studied for more than 10 years across 6 clinical trials[§] for 2 conditions.

§Earliest trials in patients with multiple sclerosis and patients with ulcerative colitis started in 2012.



Received by ~52,000 patients

Since its first approval, approximately 52,000 patients have received ZEPOSIA across both conditions.[¶]

¶As of May 2024.

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When starting any treatment, it’s important to understand what side effects are possible. Below is some of the safety information for those who took ZEPOSIA® (ozanimod) in the clinical studies.

Most common side effects

During the clinical study, people who took ZEPOSIA were asked to report side effects that they experienced. These were the most common:

- Upper respiratory tract infections
- Elevated liver enzymes
- Low blood pressure when you stand up (orthostatic hypotension)
- Painful and frequent urination (signs of urinary tract infection)
- Back pain
- High blood pressure
- Headache

Possible serious side effects

ZEPOSIA may cause serious side effects, including:

- Infections
- Progressive multifocal leukoencephalopathy (PML)
- Slow heart rate (bradyarrhythmia)
- Liver problems
- Increased blood pressure
- Breathing problems, such as shortness of breath
- Macular edema (a vision problem)
- Types of skin cancer
- Swelling and narrowing of blood vessels in the brain

These are not all the possible side effects of ZEPOSIA. Please see the [Prescribing Information](#) and [Medication Guide](#) for information on 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 healthcare provider right away.



A well-established safety profile

ZEPOSIA was studied in over 1,300 patients in clinical trials across 2 conditions (multiple sclerosis and ulcerative colitis).

One-time screenings prior to or near the start of treatment

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 tests

Near the start of your treatment



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

These routine tests will help make sure ZEPOSIA is right for you. Let your doctor know if you’ve had any of these tests within the last six months, as they may not need to be repeated.



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.



Talk with your doctor to decide if these tests can be done in the doctor’s office or at your home for eligible, commercially insured patients.

Once you’ve been approved by your healthcare provider to begin treatment, you’ll receive the ZEPOSIA Starter Kit. It will either be provided to you by your healthcare provider or delivered directly to your home.

Out-of-pocket costs may be eligible for reimbursement. There may be costs associated with some of the routine medical tests, but depending on where these tests take place, eligible, commercially insured patients may qualify for reimbursement. Additional eligibility requirements & terms and conditions apply. Please click [here](#) for more information.

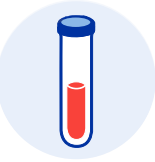
See the next page for additional information

Starting ZEPOSIA® (ozanimod): frequently asked questions



Why do I need an ECG?

To find out if ZEPOSIA is right for you, your healthcare provider will order an ECG to determine whether or not you have preexisting conditions, in which case you may be advised to visit a cardiologist.



My lymphocyte count has changed. What should I know about this?

ZEPOSIA lowers the number of white blood cells (lymphocytes) in your blood. This will usually go back to normal within 3 months of stopping treatment.



What is tyramine, and what do I need to know about it while taking ZEPOSIA?

Tyramine is a type of compound found naturally in the body and in certain foods and beverages. Consuming a large amount of tyramine while taking ZEPOSIA could lead to severe high blood pressure (hypertension).

It's recommended that people taking ZEPOSIA avoid foods and beverages that have more than 150 mg of tyramine. Some examples include 150 grams of highly aged artisan cheeses, 750 grams of commercial cheeses and cheddar, 750 grams of commercial soy sauce, and 15 liters of wines and beers.

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Getting started with ZEPOSIA® (ozanimod): a gradual start

A gradual start designed with you in mind

Once you've been approved to begin ZEPOSIA, you'll receive the ZEPOSIA Starter Kit. It includes medication for you to begin treatment and **has two parts**:

Part 1



The Starter Pack includes pills to help increase your dosage of ZEPOSIA gradually over the first 7 days of treatment. Each pill is labeled with the day and dosage. Be sure to follow the instructions written on the pack or from your UC healthcare provider and take the pills in the correct order.

Part 2

Pill size
Height: 0.56 inches
Width: 0.21 inches



The regular dosage of ZEPOSIA (orange capsules), which you'll begin taking on day 8 after completing the Starter Pack.

Additional eligibility requirements and terms & conditions apply. Please click [here](#) for more information.

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ZEPOSIA® (ozanimod) support and savings

Once ZEPOSIA has been prescribed, there are multiple ways to save on your monthly ZEPOSIA prescription costs. A Support Coordinator* from ZEPOSIA 360 Support™ can help you understand your options.



ZEPOSIA Support Coordinators available to patients

If you've been prescribed ZEPOSIA, a Support Coordinator can help answer questions about your insurance coverage and support options.



The co-pay savings offer

Eligible, commercially insured patients may pay as little as \$0 per month for ZEPOSIA with a co-pay savings offer. Additional eligibility requirements and terms and conditions apply.†



ZEPOSIA Bridge Program

If you have private or commercial insurance and are experiencing delays or issues with coverage, the ZEPOSIA Bridge Program may be able to provide ZEPOSIA to you, as needed (for up to 24 months).†



**Scan here to learn more about
ZEPOSIA 360 Support.**

*While Support Coordinators can answer questions about ZEPOSIA 360 Support, they cannot provide medical advice.

†See eligibility requirements and terms and conditions for the [co-pay savings](#) offer and the [ZEPOSIA Bridge Program](#).

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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 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.

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.

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 [Important Safety Information](#) at the end of this presentation and full [Prescribing Information](#), including [Medication Guide](#).

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Important facts about ZEPOSIA® (ozanimod)

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:
- [Clinically Isolated Syndrome \(CIS\)](#)
 - [Relapsing-Remitting MS Disease \(RRMS\)](#), and
 - Active [Secondary Progressive 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, or linezolid, which may be used to treat infections, Parkinson’s, depression, or anxiety

 **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.

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-  **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 problems. Your healthcare provider will do blood tests to check your liver’s health before you start taking ZEPOSIA.

-  **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

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

 Eating certain foods that are high (over 150 mg) in tyramine (such as aged, fermented, cured, smoked, and pickled foods) can cause your blood pressure to go up suddenly and severely (hypertensive crisis). It is important to avoid these foods while you are taking 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).

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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 **Posterior Reversible Encephalopathy Syndrome (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 changes in or loss of vision
- Sudden confusion
- Seizure

Your healthcare provider will test to see 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.

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



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.

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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

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)



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)
- Rotavirus
- Chickenpox
- Intranasal flu vaccine
- Smallpox
- 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.



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**.

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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
- ✗


Avoid certain foods that are high (over 150 mg) in tyramine, such as aged, fermented, cured, smoked, and pickled foods
- ✗

Do not skip a dose of ZEPOSIA
- ✗

Do not stop taking ZEPOSIA without talking with your healthcare provider first


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.

i 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.

Please see full [Prescribing Information](#), including [Medication Guide](#).

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