



A guide to taking your **FIRST DOSE**



*Only for people with
certain preexisting
heart conditions*

A QUICK GUIDE TO STARTING TREATMENT

ZELTASIA® (litifimod) is a once-daily pill for the treatment of adults with relapsing forms of multiple sclerosis (MS).

IMPORTANT SAFETY INFORMATION

Do not start ZELTASIA if you:

- Have had a heart attack, chest pain (also known as unstable angina), stroke or mini-stroke (also known as transient ischemic attack or TIA) or certain types of heart failure in the last 6 months

Please see Important Safety Information throughout this brochure and full Prescribing Information and Medication Guide inside back pocket.

QUICK FACTS

 **48%**
FEWER
RELAPSES & LESIONS

In a one-year study, people who took ZELTASIA® (litifimod) had 48% fewer relapses and 48% fewer lesions (T2) than people who took a leading injectable medicine (Avonex).^{*†}

78% of people who took ZELTASIA were relapse free at one year (vs 66% with a leading injectable medicine).[‡]

 **78%**
of people were
RELAPSE FREE

A total of 895 people were in the one-year study—447 people took ZELTASIA and 448 people took a leading injectable.

*Avonex (interferon beta-1a).

†People taking ZELTASIA had an Annualized Relapse Rate of 0.181 versus 0.350 with a leading injectable. Also, people taking ZELTASIA had an average of 1.465 lesions (T2) versus 2.836 with a leading injectable medicine.

‡A relapse was defined as new or worsening symptoms directly associated with MS that lasted more than twenty-four hours (after having a mostly stable neurological state for at least thirty days).

IMPORTANT SAFETY INFORMATION (cont'd)

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- Have a history or presence of certain types of irregular or abnormal heartbeat (also known as arrhythmia) that is not corrected by a pacemaker

The first dose appointment

Only for people with certain preexisting heart conditions

With some medications, it's important for people with certain preexisting heart conditions to have their heart monitored when taking their initial dose. This period of time, often called First Dose Observation, takes place at home or at a doctor's office.

With ZELTASIA, if a first dose appointment is required, your MS healthcare team will let you know. And we'll be there for you every step of the way.

IMPORTANT SAFETY INFORMATION (cont'd)

Do not start ZELTASIA if you:

- Have severe breathing problems during your sleep (also known as sleep apnea)
- Are allergic to litifimod or any of the ingredients in ZELTASIA

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Why will I be monitored and where?

The first dose of ZELTASIA® (litifimod) may cause your heart rate to slow down. So, for some people who have preexisting heart conditions, it's best to be observed by a healthcare professional for about six hours when taking the first pill. Your MS healthcare team will help determine if this is something you need.

- **A slower heart rate is not common**, but it is possible
- **Fewer than 1% of people experienced a slow heart rate** after their first dose (in clinical studies)
- **If the heart rate does slow down**, it usually doesn't last longer than six hours

IMPORTANT SAFETY INFORMATION (cont'd)

ZELTASIA may cause serious side effects, including:

- **Slow heart rate (also known as bradycardia) when you start taking ZELTASIA.** ZELTASIA can cause your heart rate to temporarily slow down, especially after you take your initial dose. Slow heart rate may occur if you restart ZELTASIA after missing more than 14 consecutive days of treatment. Prior to restarting ZELTASIA, please consult with your physician as you will need a new 7-day starter pack to minimize the risk of heart rate reductions.

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At home or the doctor's office

Your MS healthcare team will help decide if your first dose appointment will take place at a doctor's office or if a healthcare professional will be sent to your home instead.*

*Home visits for first dose appointments are not available to people living in Massachusetts, Michigan, Minnesota, and Rhode Island.



Your first dose appointment in 4 parts

During your appointment, a healthcare professional will be with you from start to finish, but it's helpful to know what's involved. Here's what you can expect:



1. Checking your heart before you start

The healthcare professional on hand will monitor your blood pressure and give you an electrocardiogram (ECG). An ECG is a common test that uses small sensors to monitor your heart and make sure it's working normally before you begin.



2. Take your first dose

Once the healthcare professional gives you the go-ahead, you'll take one ZELTASIA® (litifimod) pill with water.



3. Monitoring—once per hour

Your pulse and blood pressure will be checked every hour for the next six hours (because there's a chance your heart rate may slow down during this time). **For ideas on how to pass the time, see page 12.**



4. One final heart check

After six hours, you'll have another ECG. If it's normal, you'll be cleared to start taking ZELTASIA every day as prescribed. In the rare event that your ECG shows your heart rate is at its lowest point after six hours, you'll continue to be monitored until it's back to normal.

IMPORTANT SAFETY INFORMATION (cont'd)

Call your healthcare provider if you experience the following symptoms of slow heart rate such as:

- Dizziness
- Shortness of breath
- Lightheadedness
- Confusion
- Feeling like your heart is beating slowly or skipping beats
- Chest pain

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Getting ready for your first dose appointment

Your time is valuable, and starting off right is important. So, whether your first dose appointment takes place at home or at a doctor's office, we want to make sure you are prepared and can make the most of it. That's what these next few pages are all about.

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 **ZELTASIA**
(litifimod) | 0.92 mg capsules

Tips to help you prepare



At home

You'll be assigned a dedicated MS Nurse Navigator who will help schedule your first dose appointment. Then, **a specially trained and licensed healthcare professional will visit your home.** So, what should you do?

- **Don't stress:** With an appointment at home, you can go about your day and have a loved one right there with you. And there's no need to make special arrangements for the visiting healthcare professional (such as cleaning, cooking, or entertaining)
- **Pick a spot where equipment can be set up:** A flat surface (like a kitchen table or desk) works best
- **Stay busy or relax (it's up to you):** You'll be able to work from home or do light housework—just nothing too vigorous



At a doctor's office

Your first dose appointment requires about six hours away from home. So, how should you prepare?

- **Plan on eating:** If you'd like, pack a meal or snack—and feel free to call ahead to see if there's a cafeteria, microwave, or refrigerator
- **Bring things to do:** Whether you'll be working or watching a show, you can call ahead to see if there's Wi-Fi. **See more ideas on the next page**
- **Dress comfortably:** A loose shirt can help with the ECG, and wearing layers can help with the temperature
- **Bring any other medications you take:** There's no reason to miss a dose of anything else you should be taking during this time

Making the most of your time

Whether you want to be extra productive or just kick back, here are some ways to make the most of your appointment.



Take a look

- **Stream your favorite TV show or movie**, or download it before you go if you're headed to an office without Wi-Fi
- **Grab a book:** You may be surprised how many pages you can get through during your appointment—or listen to an audiobook instead



Get creative

Creative hobbies can help focus your mind and relieve stress. Why not try one of these?

- **Write:** Journaling is a great way to decompress, and so is writing a fictional story
- **Sketch:** You don't have to be Picasso to express yourself and calm your mind with art
- **Color:** Adult coloring books can be both fun and relaxing



Have a listen

Here are two small things you can do *before* your appointment that may help you pass the time in a fun and relaxing way:

- **Make a playlist** with all of your favorite songs—and some you haven't heard in a while
- **Download a new podcast**—ask a friend for a suggestion or search for “top podcasts” online



Get connected

It's a good time to connect with other people in the MS community or learn about live events near you. Here are just a few worth exploring:

- **Support.mymsaa.org:** Find a list of nationwide MS events
- **NationalMSSociety.org:** Click the “Get Involved” tab for MS walks and more
- **Facebook:** Like us on Facebook to join a discussion



Common questions

A first dose appointment may be new to you, and we want you to know what to expect. Here are three different ways to get answers to some of the questions you may have:

- See the list of common questions on the next page
- Ask your healthcare team
- Call a Nurse Navigator



**To reach a
Nurse Navigator:**

Call 1-833-ZELTASIA (833-XXX-XXXX)
Monday to Friday, 8 AM - 8 PM ET

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5 common questions about the first dose

1 Is it common to have a low heart rate during my first dose appointment?

In clinical studies, fewer than 1% of patients experienced a decreased heart rate. If you do experience a lower heart rate, it will most likely return to normal soon after your six-hour appointment.

2 What happens if I experience heart complications?

If heart complications or serious side effects occur during your appointment, the healthcare professional on hand will make sure that you get the help you need. If you're being monitored at home, you may be transferred to a hospital and monitored until your heart rate returns to normal.

3 Do I need to fast or avoid certain medications before taking my first dose of ZELTASIA® (litifimod)?

Fasting before your first dose of ZELTASIA is not necessary, so you can go about your day normally. It's important to discuss all of your medications with your MS healthcare team—especially before you decide to stop a medication. If your appointment takes place at a doctor's office, be sure to bring any of the medications you'd normally take during that time. There's no reason to skip a dose.

IMPORTANT SAFETY INFORMATION (cont'd)

ZELTASIA may cause serious side effects, including (cont'd):

- **Infections.** ZELTASIA can increase the risk of infections. You should not receive live vaccines during treatment with ZELTASIA and for 3 months after you stop taking ZELTASIA. Vaccines may not

4 How will I know if I'm ready to start taking ZELTASIA?

Once your first dose appointment is complete, either your healthcare professional or your MS Nurse Navigator will contact you about next steps. Typically, you'll get the go-ahead to start making ZELTASIA part of your daily routine.

5 Is there a cost for the first dose appointment?

The cost of the first dose appointment will vary depending on your insurance coverage and whether it takes place at home or at a doctor's office. **But regardless of where it takes place, your out-of-pocket costs may be reimbursed.** Your MS Nurse Navigator will explain all costs, eligibility, and the details of reimbursement.

work as well when given during treatment with ZELTASIA. ZELTASIA lowers the number of lymphocytes (a type of white blood cell) and this may lower the ability of your immune system to fight infections. This will usually go back to normal within 3 months of stopping treatment. Your health care provider should review a recent blood test of your white blood cells before you start taking ZELTASIA. months of stopping treatment. Your health care provider should review a recent blood test of your white blood cells before you start taking ZELTASIA.

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- Have severe breathing problems during your sleep (also known as sleep apnea)
- Are allergic to litifimod or any of the ingredients in ZELTASIA

ZELTASIA may cause serious side effects, including:

- **Slow heart rate (also known as bradycardia) when you start taking ZELTASIA.** ZELTASIA can cause your heart rate to temporarily slow down, especially after you take your initial dose. Slow heart rate may occur if you restart ZELTASIA after missing more than 14 consecutive days of treatment. Prior to restarting ZELTASIA, please consult with your physician as you will need a new 7-day starter pack to minimize the risk of heart rate reductions.

Call your healthcare provider if you experience the following symptoms of slow heart rate such as:

- Dizziness
- Shortness of breath
- Lightheadedness
- Confusion
- Feeling like your heart is beating slowly or skipping beats
- Chest pain

IMPORTANT SAFETY INFORMATION (cont'd)

- **Infections.** ZELTASIA can increase the risk of infections. You should not receive live vaccines during treatment with ZELTASIA and for 3 months after you stop taking ZELTASIA. Vaccines may not work as well when given during treatment with ZELTASIA. ZELTASIA lowers the number of lymphocytes (a type of white blood cell) and this may lower the ability of your immune system to fight infections. This will usually go back to normal within 3 months of stopping treatment. Your health care provider should review a recent blood test of your white blood cells before you start taking ZELTASIA.

Call your health care provider right away if you have any of these symptoms of an infection during treatment with ZELTASIA and for 3 months after your last dose of ZELTASIA:

- Fever
- Cough
- Feeling very tired
- Urinary discomfort
- Flu-like symptoms
- Rash

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IMPORTANT SAFETY INFORMATION (cont'd)

- **Progressive multifocal leukoencephalopathy (PML).** Although no cases have been seen in patients in clinical trials with ZELTASIA, PML may occur. PML is a rare brain infection that may lead to death or severe disability. If PML happens, it 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 experience any new or worsening symptoms of PML such as:

- Weakness on one side of the body
- Changes in vision
- Changes in thinking or memory
- Confusion
- Personality changes

ZELTASIA may cause serious side effects, including (cont'd):

- **A problem with your vision called macular edema.** Macular edema can cause some of the same vision symptoms as a multiple sclerosis (MS) attack (also known as “optic neuritis”). Tell your healthcare provider any time you notice vision changes during treatment with ZELTASIA. Your risk of macular edema is higher if you have diabetes or have had an inflammation of your eye called uveitis. Call your healthcare provider right away if you have any of the following:
 - Blurriness or shadows in the center of your vision
 - A blind spot in the center of your vision
 - Sensitivity to light
 - Unusually colored vision

IMPORTANT SAFETY INFORMATION (cont'd)

Before taking ZELTASIA, tell your healthcare provider about all of your medical conditions, including if you:

- Have liver problems
- Have a slow heart rate
- Have a fever or infection
- Are unable to fight infections due to a disease, or you take or have taken medicines that lower your immune system
- Have received a vaccine in the past 30 days or are scheduled to receive a vaccine. ZELTASIA may cause vaccines to be less effective
- Have macular edema or have risk factors for macular edema such as uveitis which is a type of (an inflammation of the eye) or diabetes
- Are pregnant or plan to become pregnant.
 - If you are a female who can become pregnant, you should use effective birth control during your treatment with ZELTASIA and for at least 3 months after you stop taking ZELTASIA
- Are breastfeeding or plan to breastfeed.
 - It is not known if ZELTASIA passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take ZELTASIA, are breastfeeding, or plan to breastfeed

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IMPORTANT SAFETY INFORMATION (cont'd)

Tell your healthcare provider about all the medicines you take or have recently taken, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you take or have taken medicines that affect your immune system, including corticosteroids, or other treatments for multiple sclerosis. Know the medicines you take. Keep a list of your medicines with you to show your healthcare provider and pharmacist when you get a new medicine.

ZELTASIA cause possible side effects, including:

- **Swelling and narrowing of the blood vessels in your brain.** A condition called PRES (Posterior Reversible Encephalopathy Syndrome) has happened rarely in adults taking ZELTASIA. It is not known if ZELTASIA caused this. ZELTASIA should be stopped if this condition occurs. PRES will usually get better.

However, if left untreated, it may lead to a stroke. Call your healthcare provider right away if you have any of the following symptoms:

- Sudden severe headache
 - Sudden confusion
 - Sudden loss of vision or other changes in your vision
- **Increased blood pressure.** Your healthcare provider should check your blood pressure during treatment with ZELTASIA

IMPORTANT SAFETY INFORMATION (cont'd)

- **Fetal risk.** It is not known if ZELTASIA can cause abnormalities of the fetus. You should use effective birth control during your treatment with ZELTASIA and for at least 3 months after you stop taking ZELTASIA. Call your healthcare provider if you think you may be pregnant [See “What should I tell my healthcare provider before taking ZELTASIA?”]
- **Allergic reactions.** Call your healthcare provider if you have symptoms of an allergic reaction, including a rash, itchy hives, or swelling of the lips, tongue or face

The most common side effects of ZELTASIA can include:

- Colds and sore throat
- Abnormal liver tests
- Urinary tract infections
- High blood pressure (hypertension)
- Upper respiratory tract infections

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of ZELTASIA. For more information, ask your healthcare provider or pharmacist.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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QUESTIONS?

Talk to your healthcare team

OR

call your Nurse Navigator

at 1-833-ZELTASIA (833-XXX-XXXX)

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