FOR ADULTS WITH LAMBERT-EATON MYASTHENIC SYNDROME (LEMS)

Move Forward with FIRDAPSE®

FIRDAPSE® (amifampridine) Tablets 10 mg

Please see full Important Safety Information on page 16 and accompanying full Prescribing Information.
Use this resource to understand LEMS and how FIRDAPSE® can help you move forward. You will learn how FIRDAPSE works to treat the symptoms of LEMS, how to take this medication, and how Catalyst can help and support you along the way.
BEFORE YOU TAKE FIRDAPSE®, TELL YOUR DOCTOR ABOUT ALL OF YOUR MEDICAL CONDITIONS, INCLUDING IF YOU:

- are taking another aminopyridine, such as compounded 3,4-diaminopyridine (3,4-DAP)
- have had a seizure
- have kidney problems
- have liver problems
- are pregnant or plan to become pregnant. It is not known if FIRDAPSE will harm your unborn baby. You and your doctor will decide if you should take FIRDAPSE while you are pregnant.
- are breastfeeding or plan to breastfeed. It is not known if FIRDAPSE passes into your breast milk. Talk to your doctor about the best way to feed your baby while taking FIRDAPSE.

Please see full Important Safety Information on page 16 and click for full Prescribing Information.
WHAT IS LEMS?

Lambert-Eaton myasthenic syndrome (LEMS) is a severe neuromuscular disease that causes debilitating, progressive muscle weakness and fatigue. Without treatment, people with LEMS struggle to walk and do every day activities.

LEMS is rare and can affect both men and women equally. It affects about 3,000 people in the United States. LEMS is most commonly seen in people who are 40 years or older.

About half (50%) of people with LEMS have or will develop cancer, especially small cell lung cancer. Cancer could be diagnosed either before or after a LEMS diagnosis; therefore, people with LEMS should be screened for cancer soon after a LEMS diagnosis. They should be screened again at three to six months, and every six months after that for the next two years.
WHAT CAUSES LEMS?

LEMS happens when the immune system affects communication between nerves and muscles.

Image of the Neuromuscular Junction

The neuromuscular junction (NMJ) is where nerve cells communicate with muscle cells. The synapse is the gap separating the nerve ending from the muscle cell.

Nerve cells release the neurotransmitter acetylcholine (ACh) and bind to the muscle cell. This allows for good communication between the nerve and muscle cells. When low levels of ACh are released, communication decreases and causes muscle weakness.

Calcium ions play a role in the release of ACh from the nerve. LEMS antibodies lead to lower amounts of calcium within the nerve cells, which reduces ACh release. The muscle weakness caused by this process makes it difficult for people with LEMS to walk and perform everyday activities.
LEMS SYMPTOMS

The main symptom of LEMS is muscle weakness, especially in the legs and hips. This weakness may fluctuate from day to day. Some people with LEMS may have to use assistive equipment such as a wheelchair or walker to get around.

LEMS can make it very difficult to do everyday activities, such as:
- Standing up
- Walking
- Climbing steps
- Getting into or out of a car
- Getting out of bed
- Talking
- Chewing
- Swallowing
- Lifting objects

“I no longer take the simple things for granted.”

- Wade, living with LEMS
HOW IS LEMS DIAGNOSED?

LEMS can be hard to diagnose because it is rare, and its symptoms can be similar to other more common diseases, like myasthenia gravis, multiple sclerosis, fibromyalgia, or lupus. Many people with LEMS struggle with symptoms for several years and can be misdiagnosed at first.

An early, accurate diagnosis is important because it may help people get started on treatment sooner.

LEMS is typically diagnosed through at least one of the following:

- A physical exam including evaluation of reflexes
- Bloodwork to test for certain antibodies
- An electrodiagnostic test

An electrodiagnostic test can identify problems by evaluating how well the nerves communicate with the muscles.
WHAT IS FIRDAPSE®?

FIRDAPSE is the first and only FDA-approved, evidence-based treatment for adults diagnosed with LEMS.

The goal of treatment with FIRDAPSE is to increase the amount of acetylcholine (ACh) in the neuromuscular junction (NMJ) so that ACh can improve muscle function.

1. In LEMS, antibodies block the calcium channel in nerve cells, reducing the amount of ACh released into the NMJ.

2. FIRDAPSE works by blocking the potassium channel in the nerve cell, which keeps calcium channels open longer, allowing more ACh to be released into the NMJ.

WHAT ARE THE POSSIBLE SIDE EFFECTS OF FIRDAPSE®?

- **Seizures.** You could have a seizure even if you never had a seizure before. Do not take FIRDAPSE if you have ever had a seizure. Stop taking FIRDAPSE and call your doctor right away if you have a seizure while taking FIRDAPSE.

- **Serious allergic reactions, such as anaphylaxis.** FIRDAPSE can cause serious allergic reactions. Stop taking FIRDAPSE and call your doctor right away or get emergency medical help if you have:
  - shortness of breath or trouble breathing
  - swelling of your throat or tongue
  - hives

Please see full Important Safety Information on page 16 and click for full Prescribing Information.
HOW TO TAKE FIRDAPSE®

FIRDAPSE is an oral medication that comes in 10 mg scored tablets, typically taken 3 to 4 times per day and can be taken with or without food. It’s important to take FIRDAPSE exactly as directed by your doctor.

- If you miss a dose, skip that dose and take your next dose at your next scheduled dose time.
- Do not double your dose to make up for a missed dose.
- Do not take more than 2 tablets at one time or more than 8 tablets in a 24-hour period.

How long does it take FIRDAPSE® to start working?

Once you start FIRDAPSE, your doctor may steadily increase your dose according to a regular schedule. This is called titration. Your dose is customized to you based on how well it controls your symptoms and how well you tolerate it. FIRDAPSE comes in 10 mg tablets so you may need to split your tablets into 5 mg halves during the titration period or when you reach your optimal dose.

In Phase 3 clinical studies, the average dose of FIRDAPSE was 60 mg per day. Dosage is not to exceed a maximum of 80 mg daily.

FIRDAPSE tablets are pre-scored to make them easy to split. Follow your doctor’s instructions carefully and use a pill cutter to take the appropriate dose. Working with their doctor, people are generally able to reach their optimal dose within about 4 weeks.

HOW SHOULD I TAKE FIRDAPSE®?

- Take FIRDAPSE exactly as your doctor tells you to take it. Do not change your dose of FIRDAPSE.
- Do not take FIRDAPSE together with other medicines known to increase the risk of seizures.
- If you take too much FIRDAPSE, call your doctor, 911, or go to the nearest hospital emergency room right away.

Please see full Important Safety Information on page 16 and click for full Prescribing Information.
STICKING TO A SCHEDULE

It is important to take FIRDAPSE® on a regular schedule, as prescribed by your doctor, every day

Here are some tips to help you stick to your FIRDAPSE schedule:

• Take your medicine at the same time every day
• Set an alarm to remind you of your dose time
• Divide your tablets for the week and place them in a pill container
• Keep a “medicine calendar” with your pill container and note each time you take a dose, or consider using an app on your phone to track your doses
• Keep your pill container in a place where you’re likely to see it every day to help you remember to take your medicine
• Refill your pill container at the same day/time every week

FIRDAPSE® on the go

FIRDAPSE tablets are portable and can be stored at room temperature.

• When traveling, bring extra in case your transportation is delayed
• If you’re traveling by airplane, keep your medicine in your carry-on bag instead of your checked-in baggage
  – Carry a doctor’s note explaining what FIRDAPSE is and why you take it

HOW SHOULD I STORE FIRDAPSE®?

• Store FIRDAPSE at 68°F to 77°F (20°C to 25°C).
• Safely throw away FIRDAPSE that is out of date or no longer needed.

Keep FIRDAPSE® and all medicines out of the reach of children.
Why is there Phosphate in FIRDAPSE®?

Phosphate contributes to the stability of FIRDAPSE, allowing it to be stored at room temperature. Each tablet of FIRDAPSE contains 1.5 mg of phosphorus. Phosphorus is an essential nutrient the human body needs. The recommended daily allowance of phosphorus is 700 mg per day for adults. At the maximum dose (8 tablets per day), a person would get 12 mg per day of phosphorus from FIRDAPSE, which is 1.7% of the recommended daily allowance.

WHAT IS GMP?

FIRDAPSE is manufactured based on Good Manufacturing Practices (GMP). GMP stands for good manufacturing practices, and are regulations implemented by the U.S. Food and Drug Administration (FDA) to ensure that medicines manufactured for humans meet quality standards for safety and effectiveness. Drug developers must follow GMP beginning in the second stage of clinical trials, also known as Phase 2 studies. GMP helps to ensure that:

- The medicine matches what is on the label
- The quality, purity, and strength of the medicine are consistent from batch to batch

Buildings, equipment, and processes used to manufacture pharmaceutical products are properly designed, monitored, and controlled.

For questions, please call 1-833-4-Catalyst (1-833-422-8259).
FIRDAPSE® CLINICAL STUDIES

FIRDAPSE has been shown to be effective and safe in two Phase 3 clinical studies of adult patients with LEMS.

The two Phase 3 studies with FIRDAPSE were designed as withdrawal trials. Participants began the trial taking FIRDAPSE for a period of time (known as the “run-in” phase), then were randomly selected to either continue taking FIRDAPSE or switch to placebo. Participants placed in the placebo arm then returned to FIRDAPSE.

Withdrawal trials are used when researchers want to minimize the use of a placebo for ethical or feasibility reasons, and/or in situations where the effectiveness can be determined immediately upon discontinuing the medication.

Improvements were measured with the following tests:

- Quantitative Myasthenia Gravis (QMG) is an objective assessment of arm strength, leg strength, face and neck muscle performance, swallowing, speech, grip strength, forced breathing, gaze impairment, and other measures.
- Subject Global Impression (SGI) is a patient-reported outcome measure that shows how much they improved with FIRDAPSE, compared to the placebo.

Results of these studies showed that adults with LEMS who were randomized to the placebo group (inactive medicine) had a significantly greater worsening of muscle weakness and of global impression of the effects of the study treatment on their physical well-being, compared to patients who continued FIRDAPSE.

Do not take FIRDAPSE if you:

- have ever had a seizure
- are allergic to amifampridine phosphate, or another aminopyridine
FIRDAPSE® has a favorable safety profile in clinical studies

- FIRDAPSE has been studied in 64 individuals participating in clinical trials, and in 102 participants in an expanded access program.
- In the two Phase 3 clinical trials in adult patients with LEMS, FIRDAPSE was well tolerated and the side effects were mild to moderate.
- During the three-month “run-in” portion of the Phase 3 study of FIRDAPSE, the most common adverse events (AEs) were:
  - Abnormal skin sensations, such as tingling, prickling, or burning, especially in and around the mouth, tongue, face, fingers, toes, and other body parts (62%)
  - Upper respiratory tract infection (33%)
  - Abdominal pain (14%)
  - Nausea (14%)
  - Diarrhea (14%)
  - Headache (14%)
  - Elevated liver enzymes (14%)
  - Back pain (14%)
  - High blood pressure (12%)
  - Muscle spasms (12%)

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

These are not all the possible side effects of FIRDAPSE.

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

Drugs that may interact with FIRDAPSE®

- Patients taking FIRDAPSE should:
  - Avoid drugs that increase potential for seizures, as this may increase their risk of seizures.
  - Avoid taking drugs with cholinergic effects. The concomitant use of FIRDAPSE and drugs with cholinergic effects, such as cholinergic agonists, may increase the cholinergic effects of FIRDAPSE and of those drugs, as well as increase the risk of AEs. Cholinergic effects may include: blurred vision, cramps and diarrhea, low blood pressure and decreased heart rate, nausea and vomiting, salivation and sweating, shortness of breath, and increased urinary frequency.
- Notify your healthcare provider prior to starting any new medication, including over-the-counter drugs.
MEET WADE

Before his illness, Wade never gave walking up a flight of stairs a second thought.

His job working as a high-level supervisor for highway paving operations had always required strength and grit, something he had never been short on. He also had always been up for physical adventures: scuba diving, boating, and deep-sea fishing.

That all changed when Wade came home from work one day with strange symptoms. “I had pain in both of my hips,” he says. Over the next few weeks, the changes were drastic and alarming. “My legs got weaker and weaker until I couldn’t get up from the couch and walk. I couldn’t move my jaw, so I couldn’t chew well enough to make it through a meal.” Eventually he was diagnosed with LEMS.

These days, Wade follows a regimen prescribed by his physician to take FIRDAPSE. As he reflects on his journey, he counts his blessings more than his burdens. He talks about the small successes, like a recent trip where he was able to walk, unaided, through a crowded amusement park on his own two feet.

WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT FIRDAPSE?

- FIRDAPSE can cause seizures.
  - You could have a seizure even if you never had a seizure before.
  - Do not take FIRDAPSE if you have ever had a seizure.

Stop taking FIRDAPSE and call your doctor right away if you have a seizure while taking FIRDAPSE.
MEET JERRY

Jerry prided himself on maintaining an active lifestyle, but he suddenly struggled through taxing loss of mobility and an inability to recover after a knee replacement surgery. He began daily physical therapy, but he felt like he wasn’t making progress as quickly as he hoped. Weeks went by and he was still using the walker.

With the help of his wife, Phyllis, he searched for answers and spent the next several months speaking to several neurologists and other specialists. Finally, after enduring a number of tests, including an electrodiagnostic test to evaluate the neuromuscular junction, Jerry was diagnosed with LEMS.

After taking FIRDAPSE, Jerry felt comfortable on his feet, unassisted, for the first time in months. Jerry and Phyllis have shared many adventures together, but express appreciation for slowing down and enjoying their family. They now find enjoyment in taking relaxing island cruises and visiting their two fully grown children and two grandchildren.

THE MOST COMMON SIDE EFFECTS OF FIRDAPSE® INCLUDE:

- tingling around the mouth, tongue, face, fingers, toes, and other body parts
- upper respiratory infection
- stomach pain
- nausea
- diarrhea
- headache
- increased liver enzymes
- back pain
- high blood pressure
- muscle spasms

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of FIRDAPSE.

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

Please see full Important Safety Information on page 16 and click for full Prescribing Information.
WHAT IS FIRDAPSE®?

FIRDAPSE is a prescription medicine used to treat adults 17 years of age or older with Lambert-Eaton myasthenic syndrome (LEMS). The safety and efficacy of FIRDAPSE in patients under the age of 17 has not been established.

IMPORTANT SAFETY INFORMATION

WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT FIRDAPSE?

• FIRDAPSE can cause seizures.
  – You could have a seizure even if you never had a seizure before.
  – Do not take FIRDAPSE if you have ever had a seizure.

Stop taking FIRDAPSE and call your doctor right away if you have a seizure while taking FIRDAPSE.

DO NOT TAKE FIRDAPSE IF YOU:

• have ever had a seizure.
• are allergic to amifampridine phosphate, or another aminopyridine.

BEFORE YOU TAKE FIRDAPSE, TELL YOUR DOCTOR ABOUT ALL OF YOUR MEDICAL CONDITIONS, INCLUDING IF YOU:

• are taking another aminopyridine, such as compounded 3,4-diaminopyridine (3,4-DAP)
• have had a seizure
• have kidney problems
• have liver problems
• are pregnant or plan to become pregnant. It is not known if FIRDAPSE will harm your unborn baby. You and your doctor will decide if you should take FIRDAPSE while you are pregnant.
• are breastfeeding or plan to breastfeed. It is not known if FIRDAPSE passes into your breast milk. Talk to your doctor about the best way to feed your baby while taking FIRDAPSE. Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements.

HOW SHOULD I TAKE FIRDAPSE?
• Take FIRDAPSE exactly as your doctor tells you to take it. Do not change your dose of FIRDAPSE.
• Do not take more than 2 tablets of FIRDAPSE at one time or more than 8 tablets of FIRDAPSE in a 24-hour period.
• FIRDAPSE can be taken with or without food.
• If you miss a dose of FIRDAPSE, skip that dose and take your next dose at your next scheduled dose time. Do not double your dose to make up the missed dose.
• Do not take FIRDAPSE together with other medicines known to increase the risk of seizures.
• If you take too much FIRDAPSE, call your doctor or go to the nearest hospital emergency room right away.

WHAT ARE THE POSSIBLE SIDE EFFECTS OF FIRDAPSE?
FIRDAPSE MAY CAUSE SERIOUS SIDE EFFECTS, INCLUDING:
• Seizures. See “What is the most important information I should know about FIRDAPSE?”
• Serious allergic reactions, such as anaphylaxis. FIRDAPSE can cause serious allergic reactions. Stop taking FIRDAPSE and call your doctor right away or get emergency medical help if you have:
  – shortness of breath or trouble breathing
  – swelling of your throat or tongue
  – hives

Important Safety Information is continued on page 18.
The most common side effects of FIRDAPSE include:
- tingling around the mouth, tongue, face, fingers, toes, and other body parts
- upper respiratory infection
- stomach pain
- nausea
- diarrhea
- headache
- increased liver enzymes
- back pain
- high blood pressure
- muscle spasms

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

These are not all the possible side effects of FIRDAPSE.

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

**HOW SHOULD I STORE FIRDAPSE?**

- Store FIRDAPSE at 68°F to 77°F (20°C to 25°C).
- Safely throw away FIRDAPSE that is out of date or no longer needed.

Keep FIRDAPSE and all medicines out of the reach of children.

If you would like more information, ask your doctor or pharmacist for additional information about FIRDAPSE.

The active ingredient in FIRDAPSE is amifampridine phosphate. Inactive ingredients are calcium stearate, colloidal silicon dioxide, and microcrystalline cellulose.
Jerry, living with LEMS