

FOR PEOPLE 6 YEARS OF AGE OR
OLDER LIVING WITH LAMBERT-EATON
MYASTHENIC SYNDROME (LEMS)

TAKE THE NEXT STEP WITH FIRDAPSE® (amifampridine)

Kip, living with LEMS



FIRDAPSE®
(amifampridine) Tablets 10 mg

Please see full [Important Safety Information](#)
and full [Prescribing Information](#).

Kristina, living with LEMS



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.

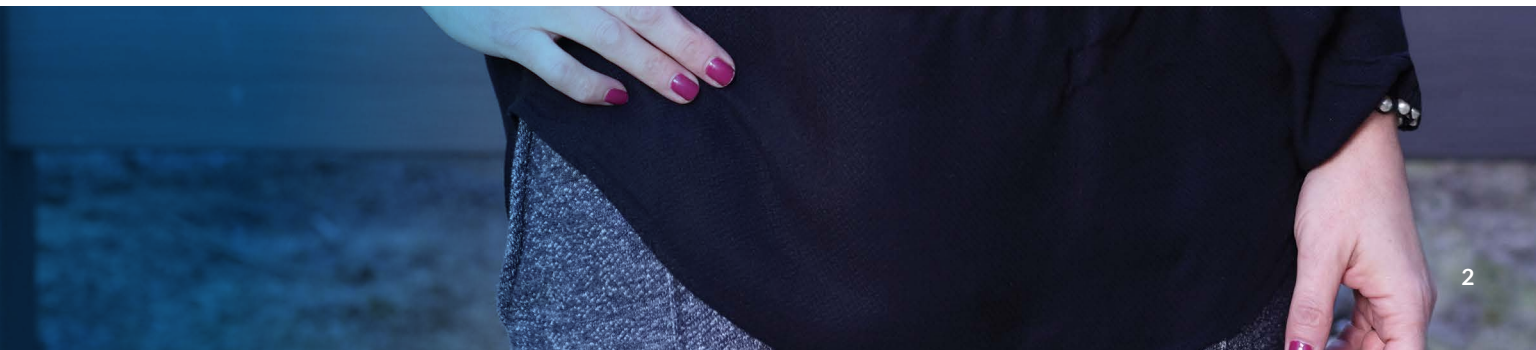


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BEFORE YOU TAKE FIRDAPSE, TELL YOUR DOCTOR ABOUT ALL OF YOUR MEDICAL CONDITIONS, INCLUDING IF YOU:

- 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
- There is a registry for women who become pregnant during treatment with FIRDAPSE. The purpose of this registry is to collect information about your health and your baby's health. Contact the registry as soon as you learn that you are pregnant, or ask your healthcare provider to contact for you by calling 855-212-5856 (toll free), contacting the Fax number 877-867-1874 (toll free), emailing the Pregnancy Coordinating Center at firdapsepregnancyregistry@ubc.com, or visiting the study website www.firdapsepregnancystudy.com
- 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.

Please see full [Important Safety Information](#) and full [Prescribing Information](#).

WHAT IS LEMS?

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



LEMS is rare. It affects at least 3,600 people in the United States.



First symptoms usually appear between ages 35 and 60.



Both men and women are affected.

About half (50%) of people with LEMS have or will develop cancer. 67% of those cases are Small Cell Lung Cancer (SCLC). Your doctor may recommend cancer screenings when you are diagnosed with LEMS, and regularly after that at their discretion.



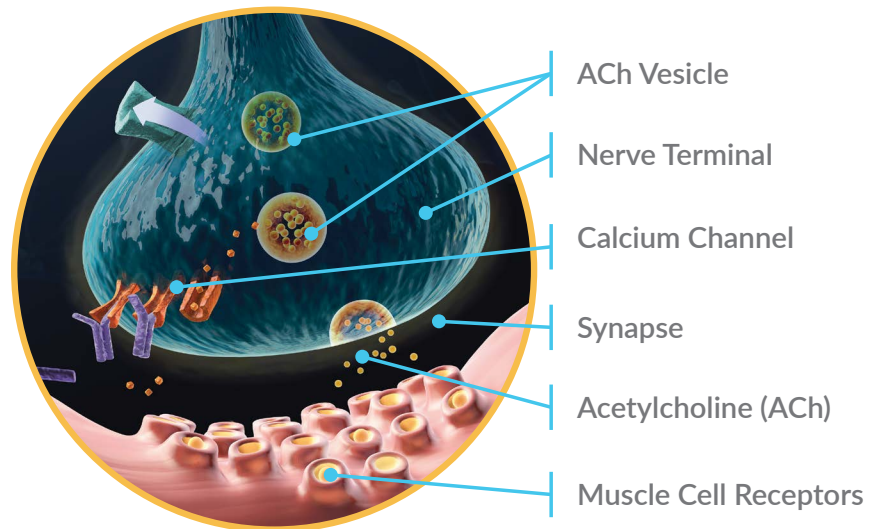
Pat, living with LEMS,
and her husband Kevin

Please see full [Important Safety Information](#)
and full [Prescribing Information](#).

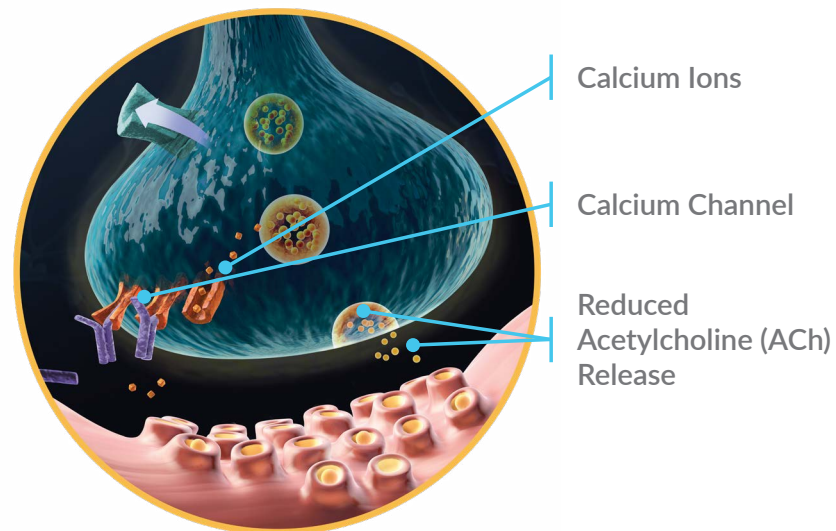
WHAT CAUSES LEMS?

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

Image of the Neuromuscular Junction (NMJ)



The **NMJ** is the point in the body where nerve cells meet muscle cells. The **synapse** is the gap separating the nerve ending from the muscle cell.



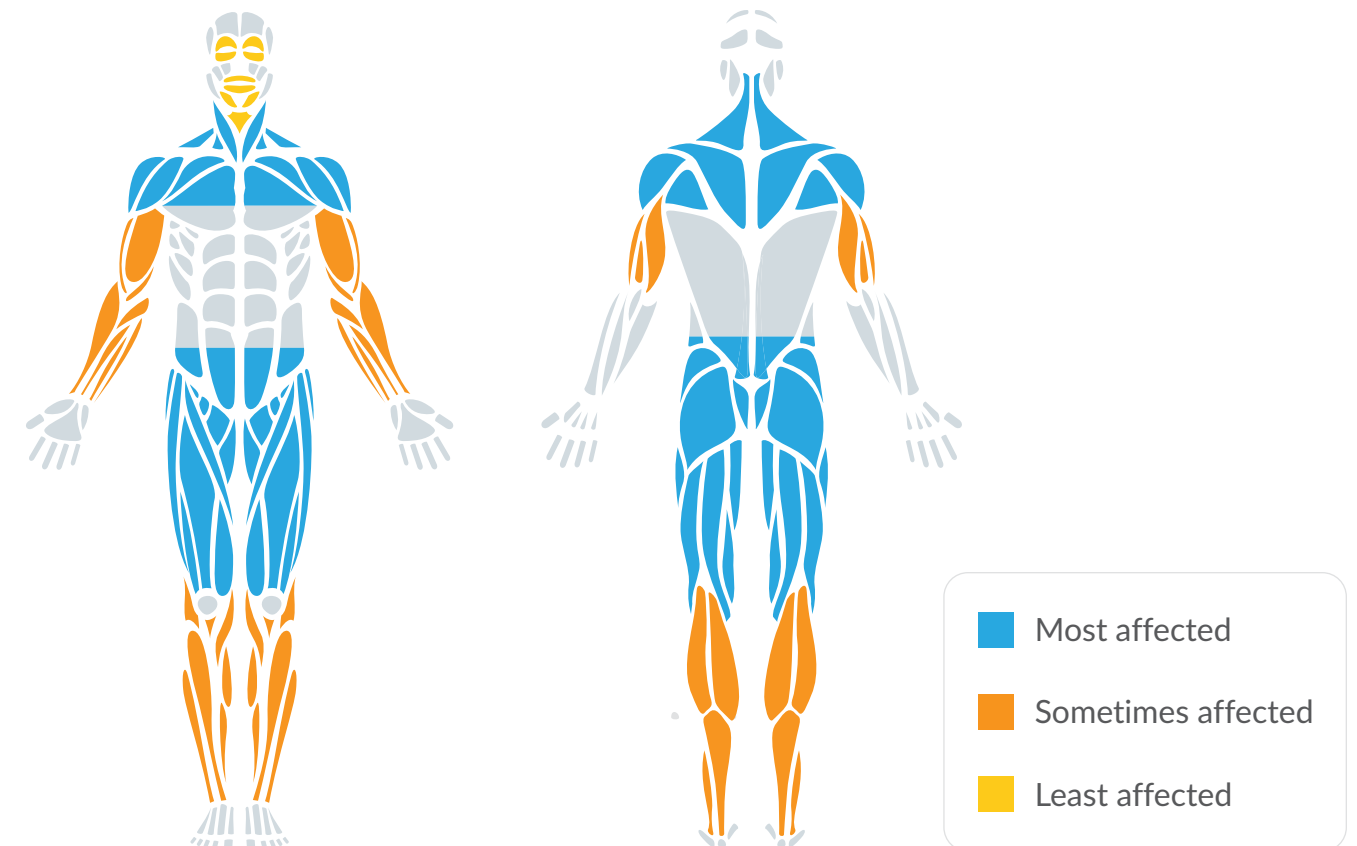
Calcium ions play a role in the release of ACh from the nerve.

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. Because of this weakness, people with LEMS are more prone to falling, and 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
- Getting into or out of a car
- Getting out of bed
- Talking
- Chewing
- Swallowing
- Lifting objects



"I have the energy
and I have the
attitude now to
do more."

– Pat, living with LEMS



HOW DOES LEMS PROGRESS?

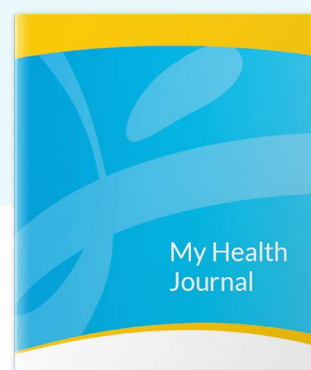
LEMS is a progressive disease. That means it can get worse over time. The first symptoms of LEMS usually occur in the hips and upper legs. As it progresses, LEMS will cause weakness in the shoulders and feet and hands. Later, it may affect the muscles used for swallowing and speech. It may also affect the eye muscles.

As LEMS progresses, it may cause symptoms not related to muscle weakness. These include dry mouth, dry eyes, constipation, impotence, and decreased sweating.



It is important to talk to your doctor if you notice changes. As your disease progresses, your doctor may adjust your medication to maintain your level of mobility.

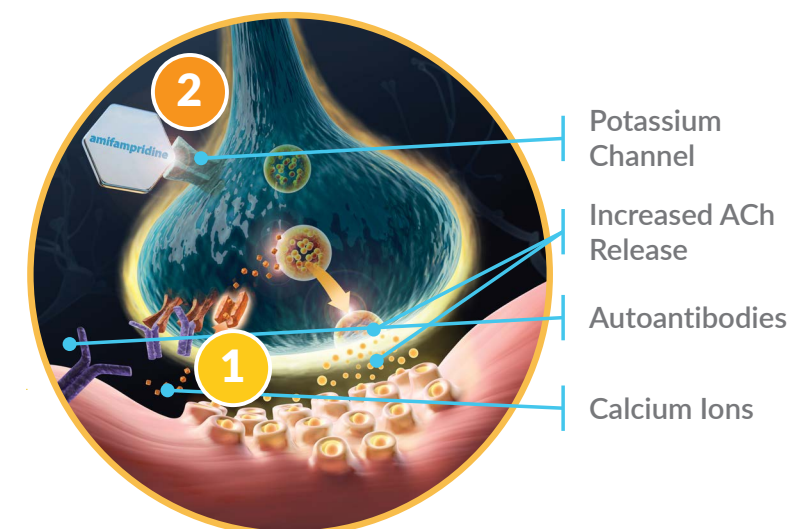
Use the FIRDAPSE My Health Journal to easily track your symptoms and response to treatment. To get a copy, call Catalyst Pathways® at 1-833-422-8259 or talk to your Patient Access Liaison (PAL).



WHAT IS FIRDAPSE®?

FIRDAPSE is the first and only FDA-approved treatment for people diagnosed with LEMS who are older than 6 years of age.

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



WHAT ARE THE POSSIBLE SIDE EFFECTS OF 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.

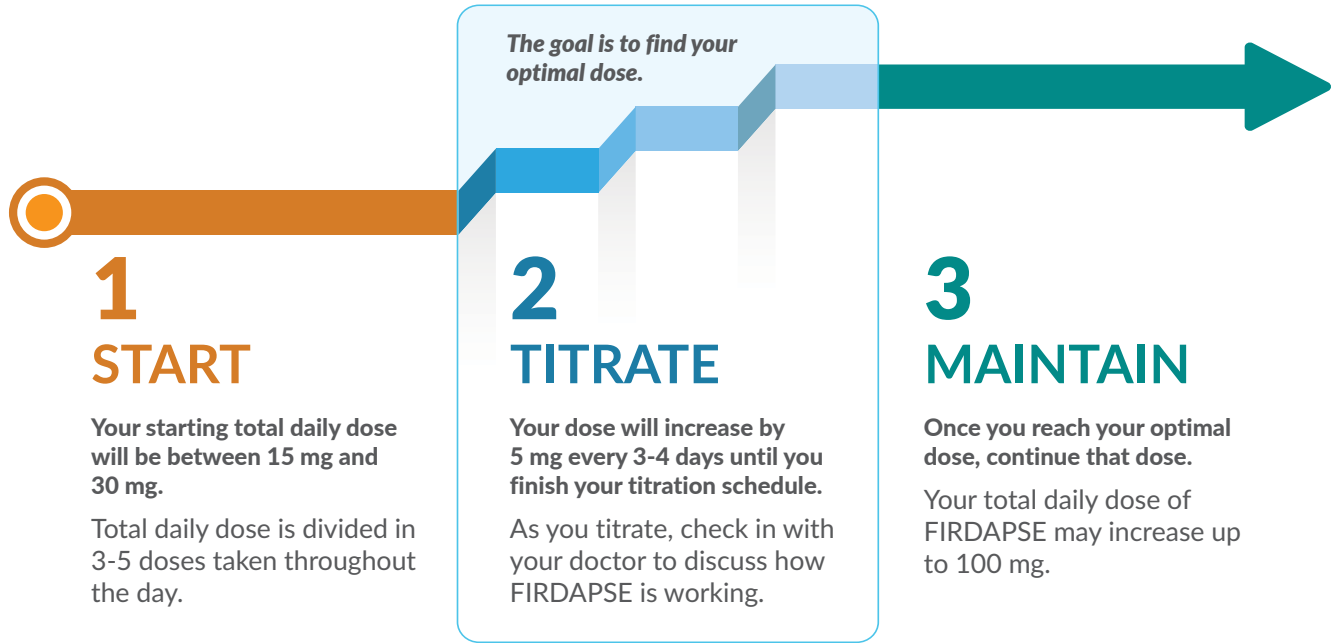
- Serious allergic reactions, such as anaphylaxis.** FIRDAPSE can cause serious allergic reactions. Stop taking FIRDAPSE and call your doctor right away or get emergency medical help if you have:
 - shortness of breath or trouble breathing
 - swelling of your throat or tongue
 - hives

Please see full [Important Safety Information](#) and full [Prescribing Information](#).

OPTIMAL DOSING STARTS WITH TITRATION

Titration is a process that uses step-by-step increases to reach the right dose for you. During titration, which happens over the first few weeks, your doctor will establish a plan to steadily increase your dose. While this process is typical for FIRDAPSE, your doctor may decide that you do not need to titrate.

Here’s how it often works for patients 6 years or older and weighing 45 kg or more*:



WHAT DOES “OPTIMAL DOSE” MEAN?
Your optimal dose is the amount of medication that gives you the best level of symptom relief at a dose you can tolerate.

In clinical trials, the average total daily dose of FIRDAPSE taken by patients was 60 mg.

*The recommended starting dosage for adult and pediatric patients with kidney impairment, liver impairment, and in poor metabolizers of N-acetyltransferase 2 (NAT2) is the lowest recommended initial dosage (15 mg daily in adults and in pediatric patients weighing 45 kg or more; 5 mg daily for pediatric patients weighing less than 45 kg). This dose should continue to be titrated to optimal symptom management and tolerability. No dosage recommendation for FIRDAPSE can be made for patients with end-stage kidney disease.



Please see dosing information for pediatric patients (age 6 and older) who weigh less than 45 kg in the full [Prescribing Information](#).

For patients with a dosage adjustment of less than 5 mg increments, or who have difficulty swallowing, or require feeding tube, a 1 mg/mL suspension (liquid solution) can be prepared. See full [Prescribing Information](#) for the detailed Instructions for Use on how to take and prepare a suspension of FIRDAPSE.



If you miss a dose, skip it altogether and take your next dose at the scheduled time. Do not take 2 doses to make up for a missed dose! Take FIRDAPSE exactly as prescribed.



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.
- 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.



Please see full [Important Safety Information](#) and full [Prescribing Information](#).

How do I create the correct dose?

FIRDAPSE comes in 10 mg tablets, but it's possible for your schedule to require smaller increments. That's why FIRDAPSE tablets are pre-scored to make them easy to split.

Work with your doctor to find the right dose for you; then follow their instructions carefully. A pill cutter (shown to the right) is provided for your convenience in the FIRDAPSE welcome kit or by your Patient Access Liaison when you join Catalyst Pathways. It is not required to use the pill cutter.

If your dose is less than 5 mg, you have trouble swallowing tablets, or a feeding tube is needed, see Medication Guide for the detailed Instructions for Use on how to take and prepare an oral suspension (liquid solution) of FIRDAPSE.



What medicines should I avoid while taking FIRDAPSE?

While taking FIRDAPSE, you should avoid medicines that:

- Increase the risk of seizures, since FIRDAPSE has been shown to increase that risk. These include medicines like certain antibiotics, anti-asthma medicines, antidepressants, and local anesthesia
 - Seizures result from abnormal electrical activity in the brain. Seizures usually last less than 2 minutes and may or may not include convulsions, or rapid and uncontrollable shaking
- Have cholinergic effects (affect the action of acetylcholine). These include:
 - Medicines that increase the effect of acetylcholine. Taking these medicines with FIRDAPSE may increase the cholinergic effects of FIRDAPSE and of these drugs. Taking these drugs together may also increase the risk of side effects
 - Medicines that decrease the effect of acetylcholine. These include atropine and scopolamine
- Block neurotransmitters, like acetylcholine, in the body. This includes botulinum toxin injections

Notify your healthcare provider prior to starting any new medication, including over-the-counter drugs.



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
- Divide your tablets for the week and place them in a pill container
- Keep your pill container in a place where you're likely to see it
- Refill your pill container at the same day/time every week
- Keep a "medicine calendar" with your pill container and note each time you take a dose

FIRDAPSE on the go

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

- When traveling, bring extra medicine in case you are delayed
- If you're traveling by airplane, keep your medicine in your carry-on; bring a doctor's note explaining what FIRDAPSE is and why you take it

How should I store FIRDAPSE?

- Store FIRDAPSE tablets at room temperature between 68°F to 77°F (20°C to 25°C)
- Safely throw away FIRDAPSE tablets that are out of date or no longer needed
- Store FIRDAPSE prepared oral suspension in the refrigerator between 36°F to 46°F (2°C to 8°C) between doses for up to 24 hours
- Safely throw away unused FIRDAPSE oral suspension after 24 hours

Please see full [Important Safety Information](#) and full [Prescribing Information](#).

DELIVERY ASSURANCE PROGRAM

Assures delivery of FIRDAPSE no matter what

Never worry about missing a dose of your medicine because of delivery issues. Our Delivery Assurance team is constantly monitoring potential obstacles and formulating alternate plans to ensure you will always get your medication on time.



The FIRDAPSE Pregnancy Registry

In conjunction with the FDA, Catalyst Pharmaceuticals has created a registry to collect information about the safety of FIRDAPSE use during pregnancy.



Contact the registry as soon as you learn that you are pregnant by calling **(855) 212-5856** or visiting www.firdapsepregnancystudy.com.



Why is there phosphate in FIRDAPSE?

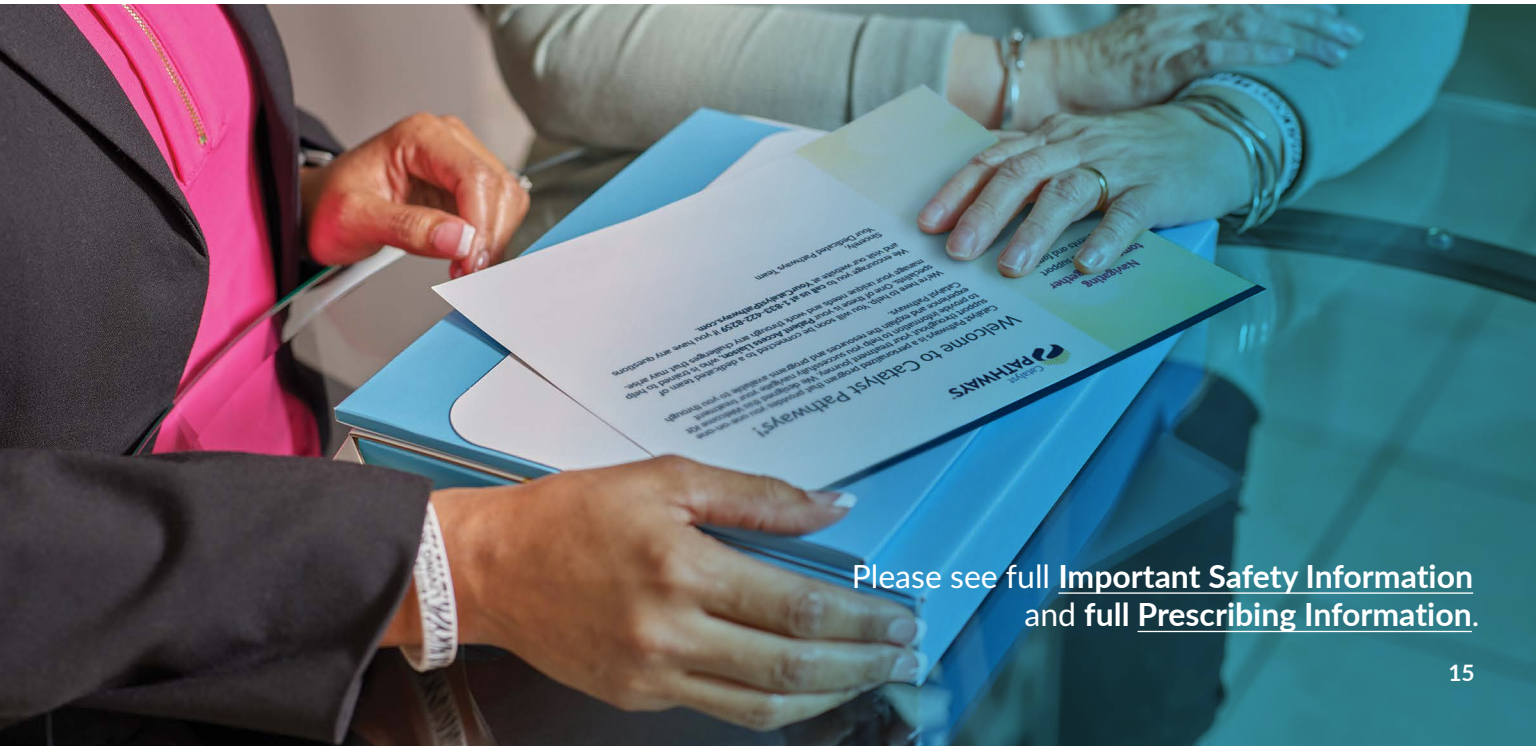
Phosphate contributes to the stability of FIRDAPSE, allowing it to be stored at room temperature. Each tablet of FIRDAPSE contains 1.5 mg of phosphorus. Phosphorus is an essential nutrient the human body needs. The recommended daily allowance of phosphorus is 700 mg per day for adults. At a dose of 8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



Please see full Important Safety Information and full Prescribing Information.

FIRDAPSE CLINICAL STUDIES

FIRDAPSE has been shown to be effective and safe in 2 Phase 3 clinical studies of adult patients with LEMS

The 2 Phase 3 studies with FIRDAPSE were designed as withdrawal trials. Participants began the trials 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 (inactive medicine). Participants placed in the placebo group were later 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 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 with 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 adult individuals participating in clinical trials and in 102 adult participants in an expanded-access program
- In the 2 Phase 3 clinical trials in adult patients with LEMS, FIRDAPSE was well tolerated and the side effects were mild to moderate
- During the 3-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 the risk of seizures, since FIRDAPSE has been shown to increase that risk. These include medicines like certain antibiotics, anti-asthma medicines, antidepressants, and local anesthesia
 - 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
 - Medicines with a cholinergic effect include Salagen (pilocarpine) and Evoxac (cevimeline)
- Notify your healthcare provider prior to starting any new medication, including over-the-counter drugs

Please see full [Important Safety Information](#) and full [Prescribing Information](#).

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 a walker.

With the help of his wife, Phyllis, he searched for answers and spent the next several months speaking to 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 starting FIRDAPSE, Jerry felt comfortable on his feet, unassisted, for the first time in months. Jerry and Phyllis have shared many adventures together and express appreciation for slowing down and enjoying their family. They now find enjoyment in taking relaxing island cruises and visiting their 2 grown children and 2 grandchildren.



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 BARBARA

If you had met Barbara prediagnosis and asked, "Who are you?", she would have told you she was a nurse with an impressive resume, a dancer, a runner, a seamstress, and a fashionista who loved to dress up.

In 2014, she suddenly found herself in an emergency room bed paralyzed from the neck down and terrified. Who was Barbara now? Her identity vanished in an instant.

After many ups and downs, her neurologist diagnosed her with LEMS. She was eventually prescribed FIRDAPSE, and her health improved. She no longer needed a cane or a walker, and her gait test improved every 6 months in balance and velocity. Her upper body strength also improved, and her reflexes returned.

Barbara now enjoys going on walks and taking care of her dog. She does her own laundry, cleaning, and shopping, which are things she had trouble doing previously. She can even dance again, in her own way. Barbara encourages others to be their own advocate. Be noisy, ask questions, and educate yourself.



THE MOST COMMON SIDE EFFECTS OF FIRDAPSE INCLUDE:

- | | |
|--|---------------------------|
| • tingling around the mouth, tongue, face, fingers, toes, and other body parts | • headache |
| • upper respiratory infection | • increased liver enzymes |
| • stomach pain | • back pain |
| • nausea | • high blood pressure |
| • diarrhea | • 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](#) and full [Prescribing Information](#).

What is FIRDAPSE?

FIRDAPSE is a prescription medicine used to treat Lambert-Eaton myasthenic syndrome (LEMS) in people 6 years of age or older. It is not known if FIRDAPSE is safe or effective in children less than 6 years of age.

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.

- There is a registry for women who become pregnant during treatment with FIRDAPSE. The purpose of this registry is to collect information about your health and your baby's health. Contact the registry as soon as you learn that you are pregnant, or ask your healthcare provider to contact for you by calling 855-212-5856 (toll free), contacting the Fax number 877-867-1874 (toll free), emailing the Pregnancy Coordinating Center at firdapsepregnancyregistry@ubc.com, or visiting the study website www.firdapsepregnancystudy.com.
- 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?

- If your dose is less than 5 mg, you have trouble swallowing tablets, or a feeding tube is needed, see the detailed Instructions for Use on how to take and prepare a suspension of FIRDAPSE.
- Take FIRDAPSE exactly as your doctor tells you to take it.
- **Do not** change your dose of FIRDAPSE.
- **Do not** stop taking FIRDAPSE without first talking to your doctor.
- FIRDAPSE tablets are scored and can be split if less than a full tablet is needed for you to get the right dose.
- 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.



IMPORTANT SAFETY INFORMATION, Continued

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

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.



Important Safety Information is continued on page 23.

How should I store FIRDAPSE?

- Store FIRDAPSE tablets at room temperature between 68°F to 77°F (20°C to 25°C).
- Safely throw away FIRDAPSE tablets that are out of date or no longer needed.
- Store FIRDAPSE prepared oral suspension in the refrigerator between 36°F to 46°F (2°C to 8°C) between doses for up to 24 hours.
- Safely throw away unused FIRDAPSE oral suspension after 24 hours.

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

General Information about the safe and effective use of FIRDAPSE

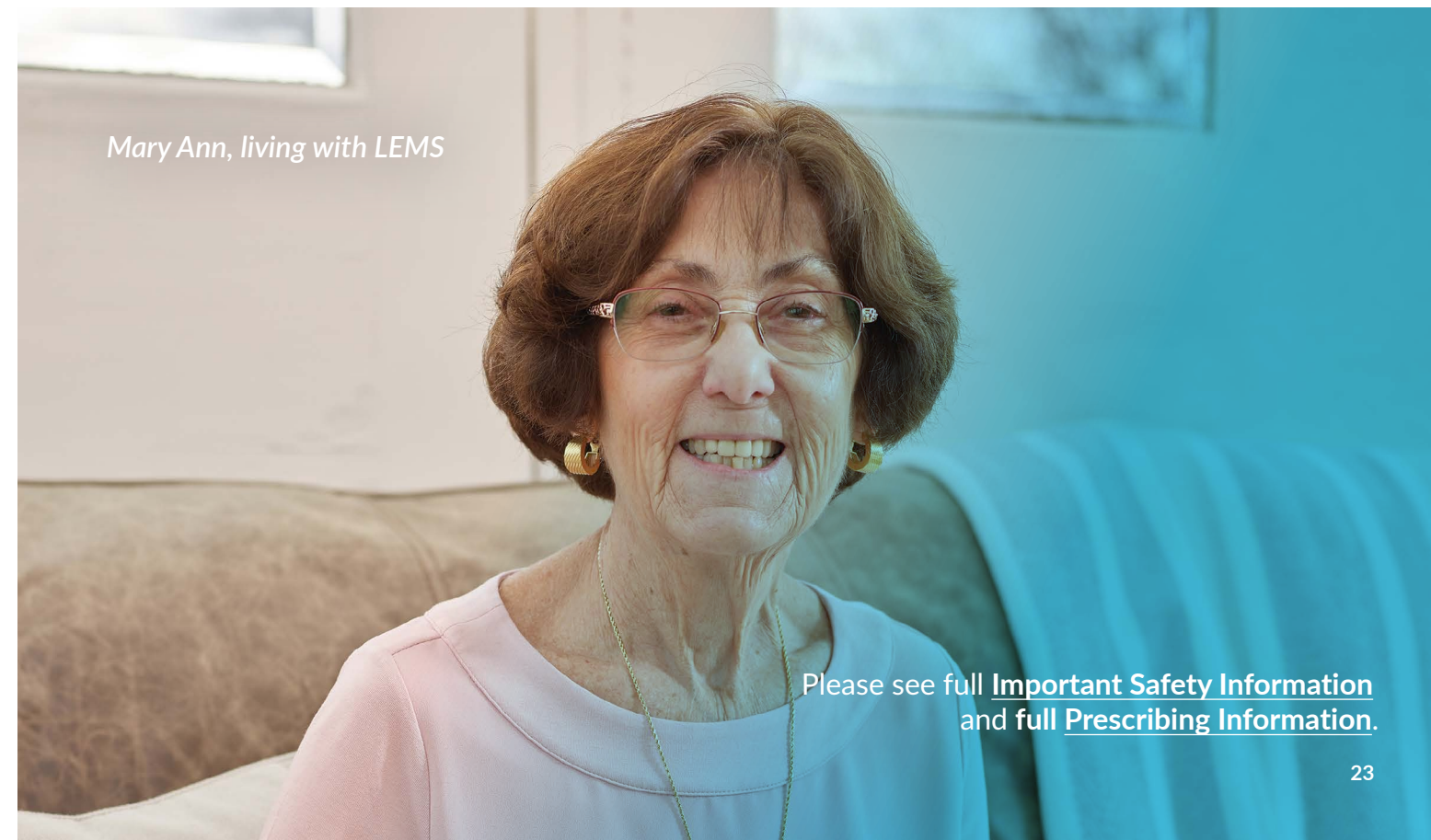
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use FIRDAPSE for a condition for which it was not prescribed. Do not give FIRDAPSE to other people, even if they have the same symptoms that you have. It may harm them. If you would like more information, talk to your doctor or pharmacist. You can ask your pharmacist or doctor for information about FIRDAPSE that is written for health professionals.

What are the ingredients in FIRDAPSE?

Active ingredient: amifampridine

Inactive ingredients: calcium stearate, colloidal silicon dioxide, and microcrystalline cellulose.

Please see full [Prescribing Information](#) for additional Important Safety Information.



Please see full [Important Safety Information](#) and full [Prescribing Information](#).

www.FIRDAPSE.com

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FIR-0594-1 November 2025