Catalyst PATHWAYS®

ENROLLMENT FORM INSTRUCTIONS

The path to Catalyst Pathways® support starts with a completed Enrollment Form

Catalyst Pathways is a comprehensive program that assists patients and their families throughout their treatment journey. It can help your patients receive delivery of FIRDAPSE® (amifampridine), determine insurance coverage, understand out-of-pocket costs, and access a variety of educational resources.

Signup can be completed in three easy steps:

STEP 1

Complete the Enrollment Form in its entirety.

- Sections 1 and 2 can be filled out by the patient or the prescriber.
- Sections 3, 4, and 5 should be filled out by the prescriber.
  - Section 4 includes Medical Criteria that should be filled out by the prescriber. This section validates the patient's diagnosis.
  - Section 5 is the prescription (Rx) and should be filled out according to the label on the FIRDAPSE package insert.
- Prescriber must sign and date where indicated on page 2.
- Patient must sign and date where indicated on page 2.
- Please include a copy of the patient's insurance card (front and back).

Catalyst Pathways provides helpful educational materials and one-on-one dosing support to help ensure that patients achieve their optimal therapeutic dose. If there are delays in verifying your patients' insurance coverage, they may be eligible to receive up to 60 days of free medication under the Catalyst Bridge program.

STEP 2

The patient must sign and date the Patient Authorization of the Enrollment Form (Section 6 on page 3) to be enrolled in Catalyst Pathways.

This step is necessary in order for Catalyst Pathways personnel to communicate with the patient's healthcare provider, insurance company, and financial assistance organizations (as necessary).

STEP 3

Fax the signed Enrollment Form to Catalyst Pathways at 1-833-422-8260.

If you have any questions, please call us at
1-833-4-CATALYST (1-833-422-8259)
7:00 AM – 7:00 PM Central Time

Catalyst PATHWAYS®

ENROLLMENT FORM

FIRDAPSE® (amifampridine) Tablets 10 mg

Fax #: 1-833-422-8260
Phone #: 1-833-4-CATALYST
(1-833-422-8259)
Please submit all 3 pages

SECTION 1 - Patient Information (to be filled in by prescriber or patient)

Last Name: _____ First Name: _____ DOB: _____ Gender: _____

Address: _____ City: _____ State: _____ ZIP: _____

Phone (please check preferred): ☐ Home: (___)_____ ☐ Work: (___)_____ ☐ Cell: (___)_____

Caregiver Name: _____ Relationship to Patient: _____ Phone #: (___)_____

Emergency Contact: _____ Phone #: (___)_____

SECTION 2 - Insurance Information (to be filled in by prescriber or patient). Please fax copies of the patient's insurance card (front and back).

☐ Patient Uninsured Primary Insurance Company Name: _____ Phone #: (___)_____

Policyholder Name: _____ Policy #: _____ Group #: _____

Prescription Card Name: _____ Phone #: (___)_____

Policy #: _____ Group #: _____

Secondary Insurance Company Name: _____ Phone #: (___)_____

Policyholder Name: _____ Policy #: _____ Group #: _____

SECTION 3 - Prescriber Information (to be filled in by prescriber only)

Prescriber Name: _____ NPI: _____ DEA: _____

Address: _____ Physician Tax ID #: _____

City: _____ State: _____ ZIP: _____ State License #: _____

Name of Contact Person: _____ Phone #: (___) _____ Preferred method of communication:

Prescriber Email: _____ Fax #: (___) _____ ☐ Fax ☐ Phone

SECTION 4 - Medical Criteria (to be filled in by prescriber only)

Primary ICD-10 Code: _____

☐ G70.80 Lambert-Eaton Syndrome, unspecified

☐ G73.1 Lambert-Eaton Syndrome in Neoplastic Disease: ☐ Small Cell Lung Cancer ☐ Other_____

☐ G70.81 Lambert-Eaton Syndrome in Disease classified elsewhere

☐ Other: _____

Previous therapy with 3,4-Diaminopyridine (3,4-DAP): ☐ Yes ☐ No

VGCC Antibody Test: ☐ Yes ☐ No If yes, include VGCC Antibody Test results: _____

Electrodiagnostic Testing for LEMS: ☐ Yes ☐ No If yes, include EMG findings: _____

Allergies: _____

OVER →

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Telephone Inquiries: 1-833-4-CATALYST (1-833-422-8259)

Catalyst PATHWAYS®

ENROLLMENT FORM
FIRDAPSE® (amifampridine) Tablets 10 mg

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Phone #: 1-833-4-CATALYST
(1-833-422-8259)
Please submit all 3 pages

Section 5 – Rx (to be filled in by prescriber only)

complete Patient Last Name: _____ Patient First Name: _____ DOB: _____

FIRDAPSE (amifampridine) 10 mg tablets (scored).
The recommended oral dosage of FIRDAPSE for adults and pediatric patients 6 years of age and older is dependent on body weight.

- Dosage should be increased every 3 to 4 days based on clinical response and tolerability
- A suspension can be prepared for patients who have dosing adjustments <5 mg, have trouble swallowing tablets, or require a feeding tube. See Instructions for Use in Prescribing Information for more information
- FIRDAPSE is contraindicated in patients with a history of seizures and hypersensitivity to amifampridine phosphate or another aminopyridine
- Paresthesia was the most common (62%) adverse reaction observed in clinical trials

Please see Section 2 of the full Prescribing Information for additional details on Dosage and Administration including missed-dosing instructions. Full Prescribing Information can be accessed here: https://firdapsehcp.com/pdfs/firdapse-pi.pdf.

In clinical trials, the average total daily dose of FIRDAPSE taken by adults was approximately 60 mg.[1]

Choose one titration schedule below, then indicate the initial daily dosage, regimen, and maximum total daily dose:

☐ RECOMMENDED TITRATION SCHEDULE A (Adult and pediatric patients 6 years of age and older and weighing 45 kg or more)

- Total daily dosage should be increased by 5 mg every 3 to 4 days based on clinical response and tolerability
- FIRDAPSE is supplied in 10 mg scored tablets

Starting total daily dose: ☐ 15 mg ☐ 20 mg ☐ 25 mg ☐ 30 mg, in **3 to 5 divided doses**

Starting **individual dose** strength: ____ mg

Initial dosing **frequency:** ☐ t.i.d. ☐ q.i.d. ☐ 5x day

Approved titration regimen: increase **total daily dosage** by 5 mg every ☐ 3 days or ☐ 4 days based on clinical response and tolerability.

Special Instructions: _____

For patients with renal impairment (creatinine clearance [CLcr] 15 to 90 mL/min), hepatic impairment, and known N-acetyltransferase 2 (NAT2) poor metabolizers, the starting dosage of FIRDAPSE should be the lowest recommended dose taken orally in divided doses (15 mg daily in adults and in pediatric patients weighing 45 kg or more). No dosage recommendation for FIRDAPSE can be made for patients with end-stage renal disease.

Titration to higher* total daily dose: The approved maximum single dose is 20 mg. The approved maximum total daily dose is 100 mg.

Maximum total daily dose: ____ mg in divided doses (the approved maximum daily dose is 100 mg)

Day Supply: ☐ 30 ☐ 90 ☐ other ____

Number of Refills authorized ____

*A higher total daily dose may be a dose greater than 60 mg. When titrating beyond a 60 mg total daily dose, patients dosing must change to q.i.d. or 5x a day frequency.

☐ RECOMMENDED TITRATION SCHEDULE B (Pediatric patients 6 years of age and older and weighing less than 45 kg)

- Total daily dosage should be increased by 2.5 mg every 3 to 4 days based on clinical response and tolerability
- FIRDAPSE is supplied in 10 mg scored tablets

Starting total daily dose: ☐ 5 mg ☐ 7.5 mg ☐ 10 mg ☐ 12 mg ☐ 15 mg, in **3 to 5 divided doses**

Starting **individual dose** strength: ____ mg

Initial dosing **frequency:** ☐ t.i.d. ☐ q.i.d. ☐ 5x day

Approved titration regimen: increase **total daily dosage** by 2.5 mg every ☐ 3 days or ☐ 4 days based on clinical response and tolerability.

Special Instructions: _____

For patients with renal impairment (creatinine clearance [CLcr] 15 to 90 mL/min), hepatic impairment, and known N-acetyltransferase 2 (NAT2) poor metabolizers, the starting dosage of FIRDAPSE should be the lowest recommended dose taken orally in divided doses (5 mg daily for pediatric patients weighing less than 45 kg). No dosage recommendation for FIRDAPSE can be made for patients with end-stage renal disease.

Titration to higher total daily dose: The approved maximum single dose is 10 mg. The approved maximum total daily dose is 50 mg.

Maximum total daily dose: ____ mg in divided doses (the approved maximum daily dose is 50 mg)

Day Supply: ☐ 30 ☐ 90 ☐ other ____

Number of Refills authorized ____

☐ RECOMMENDED TITRATION SCHEDULE C (For patients who do not fit the criteria for the categories above and require individualized dosing)

- FIRDAPSE is supplied in 10 mg scored tablets

Starting total daily dose: ____ mg in **3 to 5 divided doses**

Starting **individual dose** strength: ____ mg

Initial dosing **frequency:** ☐ t.i.d. ☐ q.i.d. ☐ 5x day

Approved titration regimen: increase **total daily dosage** by 5 mg every ☐ 3 days or ☐ 4 days based on clinical response and tolerability.

Special Instructions: _____

Refer to schedules **A** and **B** above for **approved maximum single dose** and **approved maximum total daily dose.**

Day Supply: ☐ 30 ☐ 90 ☐ other ____

Number of Refills authorized ____

Reference: 1. Data on file, Catalyst Pharmaceuticals.

By signing below, I certify that (1) the above therapy is medically necessary and in the best interest of the named patient; (2) I have received the appropriate permission from the patient (or the patient's Legal Representative) and met any other applicable legal or regulatory requirements such as those imposed under the Health Insurance Portability and Accountability Act of 1996 and/or state law needed to release the above information to Catalyst Pharmaceuticals, Inc. (Catalyst) and its agents; (3) I have obtained the patient's authorization to release the above information and such other information as may be required by AnovoRx Manufacturer Services, LLC, as Catalyst's agent, and its employees to assist in obtaining coverage for this drug; and (4) I appoint AnovoRx Manufacturer Services, LLC, as my agent for the purpose of conveying this prescription to the appropriate dispensing pharmacy, verifying the patient's insurance coverage for FIRDAPSE (amifampridine) 10 mg tablets, providing information regarding payer coverage and benefits and how to prepare prior authorization requests, coverage determination appeals, or other coverage issues, and providing me and my patient with educational and support services associated with FIRDAPSE (amifampridine) 10 mg tablets.

Prescriber Signature: sign _____ Date: _____

I have read and agree to the Patient Authorization included on the next page.

Patient/Legal Guardian Signature: sign _____ Date: _____

Signatory's Relationship to Patient: _____

SECTION 6 - Patient Authorization

Please refer to our full Privacy Policy at www.catalystpharma.com/privacy-policy/

Print Patient Name: _____ Date of Birth: _____

By signing this Authorization, I authorize my healthcare providers, health plans, and pharmacy providers and any other custodian of my healthcare records to disclose my personal health information, including, but not limited to, information relating to my medical condition, treatment, care management, and health insurance, as well as all information provided on this form and any information about my prescriptions ("Personal Health Information"), to Catalyst Pharmaceuticals, Inc. and its representatives, agents, contractors, and affiliates (collectively, "Catalyst") in order for Catalyst to provide product support services. I further authorize Catalyst to use and disclose my Personal Health Information to third parties, including, but not limited to, specialty pharmacies, health plans, insurance companies, and patient assistance programs solely for such Catalyst Pathways product support services, including, but not limited to, investigating insurance coverage, providing financial assistance for copay or out-of-pocket payments, eligibility for free medication supply, coordinating delivery of medication and communicating with me by mail, email, or telephone about my medical condition, treatment, care management, and health insurance.

I understand that my Personal Health Information, once disclosed to third parties under this Authorization, may no longer be protected by state and federal privacy laws and could be disclosed by Catalyst as well as other recipients of the information to others not identified in this Authorization as long as it is used for the purposes outlined herein. I understand that signing this Authorization is voluntary but that if I decide not to sign this Authorization, I will not be eligible to join Catalyst Pathways and receive its services and benefits for which I may qualify. I also understand that my treatment, payment, enrollment in a health plan, or eligibility for insurance benefits, including my access to therapy, is not conditioned on my signing this Authorization—only my eligibility for Catalyst Pathways. I understand that I am entitled to a signed copy of this Authorization.

I may choose to cancel this Authorization at any time and stop receiving Catalyst Pathways services, and, if I choose to cancel, I must do so in writing by sending notice of my cancellation to the following address: Catalyst Pathways, c/o AnovoRx Manufacturer Services, LLC, 1710 N Shelby Oaks Dr., #3, Memphis, TN 38134. Catalyst Pathways personnel will convey the cancellation to all of my healthcare providers, health plans, and pharmacy providers that have previously received the Authorization. I also understand, however, that any such cancellation will not apply to any information already used or disclosed based on this Authorization prior to receipt of the cancellation by Catalyst. This Authorization expires five (5) years from the date signed below.

I agree to my enrollment in the Catalyst Copay Card Program; if confirmed as eligible, I understand that Copay Card information will be sent to my specialty pharmacy, along with my prescription and any assistance with my cost-sharing or copayment for FIRDAPSE will be made in accordance with the Program Terms and Conditions. I understand that Catalyst may provide compensation to my pharmacy provider in exchange for data and/or Catalyst Pathways services that the pharmacy provides to me.

(The following checkboxes describe additional <u>voluntary</u> programs in which you may choose to participate.)

check ☐ I acknowledge that by checking this box, I expressly consent to receive text messages from or on behalf of the Catalyst Pathways Patient Support activities at the mobile number(s) that I provide. Not checking this box will only allow Catalyst Pathways to communicate with me through calls, emails, and the mail.

I confirm that I am the subscriber for the mobile telephone number(s) provided, and I agree to notify Catalyst Pathways promptly if any of my numbers change in the future. I understand that my wireless service provider's message and data rates may apply. I understand that I can opt out from future text messages by responding STOP to any text. I also understand that additional text messaging terms and conditions may be provided to me in the future as part of an opt-in confirmation text message.

check ☐ I would like to receive information and educational resources about FIRDAPSE, as well as updates from Catalyst Pharmaceuticals. I acknowledge that I may opt out of receiving communications by calling 1-833-4-CATALYST (1-833-422-8259) or unsubscribing at the link provided in future communications.

Email Address: _____

Patient/Legal Guardian Signature: sign _____ Date: _____

I, the patient or legal guardian(s), authorize the following individual(s) to act as my representative(s). These individual(s) have my full permission to obtain and disclose personal and medical information about me to Catalyst and its agents and contractors.

Patient/Legal Guardian Signature: sign _____ Date: _____

Name of Patient Representative: _____ Relationship to Patient: _____

Home Phone #: (____)_____ Mobile #: (____)_____

PLEASE FAX TO 1-833-422-8260

Telephone Inquiries: 1-833-4-CATALYST (1-833-422-8259)

MEDICATION GUIDE
FIRDAPSE® (FIR-dapse)
(amifampridine)
tablets, for oral use

Read this Medication Guide before you start taking FIRDAPSE and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment.

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.

What is FIRDAPSE?

FIRDAPSE is a prescription medicine used to treat Lambert-Eaton myasthenic syndrome (LEMS) in people 6 years of age and older.

It is not known if FIRDAPSE is safe or effective in children less than 6 years of age.

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 doctor 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 5mg, 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.

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.

How should I store FIRDAPSE?

- Store FIRDAPSE tablets at room temperature between 68ºF to 77ºF (20ºC to 25ºC).
- 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.

Distributed by Catalyst Pharmaceuticals, Inc., Coral Gables, FL 33134
For more information, go to www.YourCatalystPathways.com or call 1-833-422-8259

This Medication Guide has been approved by the U.S. Food and Drug Administration Revised: 5/2024

Instructions for Use

FIRDAPSE (FIR-dapse)

(amifampridine) tablets

for oral use

This Instructions for Use contains information on how to mix and use FIRDAPSE prepared suspension. The FIRDAPSE prepared suspension can be used for people who are prescribed a dosage that cannot be obtained with whole or half tablets, who have trouble swallowing tablets, or who have a feeding tube.

Prepare FIRDAPSE oral suspension each day.

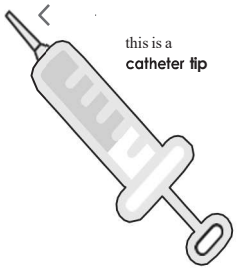
Supplies you will need:

You can get these supplies at your local pharmacy.

your FIRDAPSE tablets

empty bottle with cap (50-100 mL recommended)

sterile water



oral syringe with catheter tip (10mL, may require smaller syringe for dosing)

Instructions to make a 1 mg/mL suspension:

Important:

- **Do not use** any foods or liquids other than sterile water to mix FIRDAPSE.
- You can prepare each dose separately or all of your doses for the day at one time.

Step 1

Place the number of FIRDAPSE tablets you need for your dose or doses in a bottle.

Step 2

For each tablet, add 10 mL of water to the bottle. **Measure** the water with an oral syringe, and **inject** the water into the bottle.

Note: Depending on the number of tablets and the size of the syringe, you may need to measure and inject the water more than one time.

Step 3

then shake well

30
seconds

Secure the cap back on the bottle. **Wait** for 5 minutes. **Shake well** for 30 seconds.

Instructions to administer the prepared suspension:

Important:

- **Prepare** fresh suspensions daily.
- If you prepare all of your doses for the day at one time, **refrigerate** the suspension between doses. **Shake** well before drawing up each dose.

OPTION 1 To administer by **mouth**:

Step 4

Remove the bottle cap and use an oral syringe with a catheter tip to **measure** the prescribed dose.

Step 5

Push syringe plunger to administer by mouth.

Note: Depending on the dose and size of syringe, you may need to **repeat** steps 4 and 5 until the prescribed dose is given.

OPTION 2 To administer by **feeding tube**:

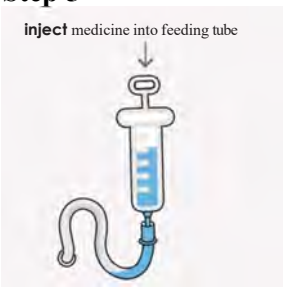
Important:

- **Do not use** any foods or liquids other than sterile water to mix FIRDAPSE.
- **Use only an oral syringe with a catheter tip to give FIRDAPSE through the feeding tube.** Talk to your healthcare provider about the size catheter tipped syringe you should use.

Step 4

Remove the bottle cap and use an oral syringe with a catheter tip to **measure** the prescribed dose.

Step 5



Inject the medicine using the oral syringe with a catheter tip into the feeding tube right away.
Note: Depending on the dose and size of syringe, you may need to **repeat** steps 4 and 5 until the prescribed dose is given.

Step 6

To flush the feeding tube: **Refill** the syringe with 10 mL of sterile water.

Step 7

Shake the syringe, **insert** the catheter tip into the feeding tube to flush any remaining medicine from the feeding tube into the stomach.

How should I store FIRDAPSE?

Firdapse tablets:

- Store FIRDAPSE tablets at room temperature between 68ºF to 77ºF (20ºC to 25ºC).
- Safely throw away FIRDAPSE tablets that are out of date or no longer needed.

Firdapse prepared suspension:

- 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.

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