

**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 adults.

It is not known if FIRDAPSE is safe or effective in children.

**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
- 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 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

**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.**

#### **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](http://www.YourCatalystPathways.com) or call 1-833-422-8259

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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