



5 2 4 5 8 5 2

Dispense with Medication Guide available at:
<https://www.sunpharma.com/usa/products>

MEDICATION GUIDE

Dalfampridine (dal-FAM-pri-deen) Extended-Release Tablets

Read this Medication Guide before you start taking dalfampridine extended-release tablets 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 dalfampridine extended-release tablets?

Dalfampridine extended-release tablets can cause seizures.

- You could have a seizure even if you never had a seizure before.
- Your chance of having a seizure is higher if you take too many dalfampridine extended-release tablets or if your kidneys have a mild decrease of function, which is common after age 50.
- Your doctor may do a blood test to check how well your kidneys are working, if that is not known before you start taking dalfampridine extended-release tablets.
- Do not take dalfampridine extended-release tablets if you have ever had a seizure.
- Before taking dalfampridine extended-release tablets tell your doctor if you have kidney problems.
- Take dalfampridine extended-release tablets exactly as prescribed by your doctor. See “How should I take dalfampridine extended-release tablets?”

Stop taking dalfampridine extended-release tablets and call your doctor right away if you have a seizure while taking dalfampridine extended-release tablets.

What are dalfampridine extended-release tablets?

Dalfampridine extended-release tablets are prescription medicines used to help improve walking in adults with multiple sclerosis (MS). This was shown by an increase in walking speed.

It is not known if dalfampridine extended-release tablets are safe or effective in children less than 18 years of age.

Who should not take dalfampridine extended-release tablets?

Do not take dalfampridine extended-release tablets if you:

- have ever had a seizure
- have certain types of kidney problems
- are allergic to dalfampridine (4-aminopyridine), the active ingredient in dalfampridine extended-release tablets

What should I tell my doctor before taking dalfampridine extended-release tablets?

Before you take dalfampridine extended-release tablets, tell your doctor if you:

- have any other medical conditions
- are taking compounded 4-aminopyridine (fampridine, 4-AP)
- are taking any other medicines, including over-the-counter medicines such as cimetidine
- are pregnant or plan to become pregnant. It is not known if dalfampridine extended-release tablets will harm your unborn baby.
- are breast-feeding or plan to breast-feed. It is not known if dalfampridine passes into your breast milk. Talk with your healthcare provider about the best way to feed your baby if you take dalfampridine extended-release tablets.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements.

Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist when you get a new medicine.

How should I take dalfampridine extended-release tablets?

- Take dalfampridine extended-release tablets exactly as your doctor tells you to take it. Do not change your dose of dalfampridine extended-release tablets.
- Take one dalfampridine extended-release tablet 2 times each day about 12 hours apart. Do not take more than 2 dalfampridine extended-release tablets in a 24-hour period.
- **Take dalfampridine extended-release tablets whole. Do not break, crush, chew or dissolve dalfampridine extended-release tablets before swallowing. If you cannot swallow dalfampridine extended-release tablets whole, tell your doctor.**
- Dalfampridine is released slowly over time. If the tablet is broken, the medicine may be released too fast. This can raise your chance of having a seizure.
- Dalfampridine extended-release tablets can be taken with or without food.
- If you miss a dose of dalfampridine extended-release tablets, do not make up the missed dose. Do not take 2 doses at the same time. Take your next dose at your regular scheduled time.
- If you take too many dalfampridine extended-release tablets, call your doctor or go to the nearest hospital emergency room right away.

- Do not take dalfampridine extended-release tablets together with other aminopyridine medications, including compounded 4-AP (sometimes called 4-aminopyridine, fampridine).

What should I avoid while taking dalfampridine extended-release tablets?

Dalfampridine extended-release tablets may cause dizziness or vertigo. If you have these symptoms, do not drive, operate machinery, or do other dangerous activities.

What are the possible side effects of dalfampridine extended-release tablets?

Dalfampridine extended-release tablets may cause serious side effects, including:

- serious allergic reactions. Stop taking dalfampridine extended-release tablets 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

See “What is the most important information I should know about dalfampridine extended-release tablets?”

The most common side effects of dalfampridine extended-release tablets include:

- urinary tract infection
- trouble sleeping (insomnia)
- dizziness
- headache
- nausea
- weakness
- back pain
- problems with balance
- multiple sclerosis relapse
- burning, tingling or itching of your skin
- irritation in your nose and throat
- constipation
- indigestion
- pain in your throat

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 dalfampridine extended-release tablets. For more information, ask your doctor or pharmacist.

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

How should I store dalfampridine extended-release tablets?

- Store dalfampridine extended-release tablets at 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (59° and 86°F).
- Safely throw away dalfampridine extended-release tablets those are out of date or no longer needed.

Keep dalfampridine extended-release tablets and all medicines out of the reach of children.

General Information about the safe and effective use of dalfampridine extended-release tablets

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use dalfampridine extended-release tablets for a condition for which it was not prescribed. Do not give dalfampridine extended-release tablets to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about dalfampridine extended-release tablets. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about dalfampridine extended-release tablet that is written for health professionals.

For more information, call 1-800-818-4555.

What are the ingredients in dalfampridine extended-release tablets?

Active ingredient: dalfampridine, USP (previously called fampridine)

Inactive ingredients: hypromellose, povidone, microcrystalline cellulose and magnesium stearate. The film-coating contains hypromellose, talc, ethyl cellulose, triacetin and titanium dioxide. The imprinting ink contains shellac glaze, iron oxide black, n-butyl alcohol, propylene glycol and ammonium hydroxide.

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

Distributed by:

Sun Pharmaceutical Industries, Inc.
Cranbury, NJ 08512



Manufactured by:

Sun Pharmaceutical Industries Limited
Survey No. 1012, Dadra-396 193,
U.T. of D & NH and Daman & Diu, India.

5245852
ISS. 10/2023