

ampyra[™]
(dalfampridine) **10 mg**
EXTENDED RELEASE TABLETS

Access to AMPYRA

AMPYRA (dalfampridine) Extended Release Tablets are distributed through specialty pharmacies.

- 1** The physician and patient complete the enrollment form.
- 2** The physician's office faxes the completed enrollment form to AMPYRA Patient Support Services at 1-888-883-3053.
- 3** An individual from AMPYRA Patient Support Services confirms the patient's insurance and eligibility for co-pay mitigation and forwards the prescription to a specialty pharmacy.
- 4** A staff member from the specialty pharmacy contacts the patient to set up delivery of AMPYRA and will also contact the patient prior to each refill date to coordinate the next shipment.

You can contact AMPYRA Patient Support Services by calling 1-888-881-1918 Monday through Friday, from 8 AM to 8 PM ET.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch <http://www.fda.gov/Safety/MedWatch/default.htm>, or call 1-800-FDA-1088.

Please see accompanying full Prescribing Information and Medication Guide in pocket on this page.

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T H E R A P E U T I C S

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ampyra[™]
(dalfampridine) **10 mg**
EXTENDED RELEASE TABLETS

AMPYRA[™] (dalfampridine) is indicated as a treatment to improve walking in patients with multiple sclerosis (MS). This was demonstrated by an increase in walking speed.

Dosing and Administration Guide

Please see accompanying full Prescribing Information and Medication Guide in back pocket.

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Importance of Appropriate Dosing

ORAL TABLET

- The maximum recommended dose of AMPYRA is one 10 mg tablet twice daily, taken approximately 12 hours apart and should not be exceeded.

AMPYRA is only available in 10 mg tablets

Tablet shown actual size



Enlarged to show tablet detail. AMPYRA is available as a non-scored tablet debossed with "A10" on one side.



- No additional benefit was demonstrated at doses greater than 10 mg twice daily.
- AMPYRA can cause seizures.
- The risk of seizures increases with increasing AMPYRA doses.
- Discontinue AMPYRA use if seizure occurs.
- In clinical trials, therapeutic response was generally observed within 6 weeks.*

Important Safety Information

CONTRAINDICATIONS

AMPYRA is contraindicated in the following conditions: History of seizure or moderate or severe renal impairment.

*Data on file. Acorda Therapeutics, Inc.

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AMPYRA 10 mg, 1 tablet PO q12h

- Adverse reactions and discontinuations because of adverse reactions were more frequent at higher doses.
- Patients should not take more than 2 tablets of AMPYRA in a 24-hour period.
 - Patients should not take double or extra doses if a dose is missed.
- Tablets should only be taken whole; do not divide, crush, chew, or dissolve.
- AMPYRA can be taken with or without food.

Important Safety Information

WARNINGS AND PRECAUTIONS

AMPYRA should not be taken with other forms of 4-aminopyridine (4-AP, fampridine), since the active ingredient is the same.

Patients should discontinue use of any product containing 4-aminopyridine prior to initiating treatment with AMPYRA in order to reduce the potential for dose-related adverse reactions, including seizures.

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A Therapeutic Option for a Wide Range of Patients

IN TWO PHASE 3 CLINICAL TRIALS, AMPYRA IMPROVED WALKING IN PATIENTS:

- Across all 4 major types of MS
 - ☑ Relapsing remitting
 - ☑ Primary progressive
 - ☑ Secondary progressive
 - ☑ Progressive relapsing
- Without regard to concomitant medications including immunomodulatory drugs.
- With no differences in effectiveness detected based on degree of impairment, age, gender, or body mass index.
- With EDSS scores ranging from 2.5 to 7.0.
- AMPYRA improved walking speed in significantly more patients than placebo in 2 clinical trials (34.8% vs. 8.3% and 42.9% vs. 9.3%), $p < 0.001$ in both.

Important Safety Information

RENALLY IMPAIRED PATIENTS

AMPYRA is contraindicated in patients with moderate or severe renal impairment ($\text{CrCl} \leq 50$ mL/min); the risk of seizures in patients with mild renal impairment (CrCl 51-80 mL/min) is unknown, but AMPYRA plasma levels in these patients may approach those seen at a dose of 15 mg twice daily, a dose that may be associated with an increased risk of seizures; estimated CrCl should be known before initiating treatment with AMPYRA.

Please see accompanying full Prescribing

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Important Safety Information

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category C

There are no adequate and well-controlled studies of AMPYRA in pregnant women. AMPYRA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing mothers

It is not known whether dalfampridine is excreted in human milk.

Pediatric use

Safety and effectiveness of AMPYRA in patients younger than 18 years of age have not been established.

Geriatric use

Clinical studies of AMPYRA did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Because elderly patients are more likely to have decreased renal function, it is particularly important to know the estimated creatinine clearance (CrCl) in these patients.

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Urinary tract infections were reported more frequently as adverse reactions in patients receiving AMPYRA 10 mg twice daily compared to placebo.

DRUG INTERACTIONS

In humans, dalfampridine is eliminated predominately unchanged by the kidneys. No clinically significant drug interaction was identified.

Interferon. Dalfampridine kinetics were not affected by co-administration of subcutaneous injections of 8 million units interferon beta-1b.

Baclofen. No pharmacokinetic drug-drug interaction was observed with co-administration of dalfampridine 15 mg and baclofen 10 mg.

OVERDOSAGE

Three cases of overdose were reported in controlled clinical trials with AMPYRA, involving two MS patients. The first patient took six times the currently recommended dose (60 mg) and was taken to the emergency room with altered mental state. The second patient took 40 mg doses on two separate occasions. In the first instance, she experienced a complex partial seizure and, in the second instance, a period of confusion. Both patients recovered by the following day without sequelae.

ADVERSE REACTIONS

Adverse reactions with an incidence $\geq 2\%$ of AMPYRA treated MS patients, and more frequent with AMPYRA compared to placebo in controlled clinical trials.

Adverse Reaction	Placebo (N=238)	AMPYRA 10 mg q12h (N=400)
Urinary tract infection	8%	12%
Insomnia	4	9
Dizziness	4	7
Headache	4	7
Nausea	3	7
Asthenia	4	7
Back pain	2	5
Balance disorder	1	5
Multiple sclerosis relapse	3	4
Paresthesia	3	4
Nasopharyngitis	2	4
Constipation	2	3
Dyspepsia	1	2
Pharyngolaryngeal pain	1	2

- Only 4% (15/400) of patients treated with AMPYRA discontinued due to treatment-emergent adverse events, compared with 2% (5/238) for placebo in 3 controlled clinical studies.

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