

Proprietary name:	Fampridine 10 mg Ascend
Dosage form:	Extended-release tablet
Active Ingredient:	Fampridine
Strength per dosage unit:	10 mg per tablet

1.3.2.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

Fampridine 10 mg Ascend Extended-release tablet

Fampridine 10 mg

Sugar-free.

Each extended-release tablet contains 10 mg of fampridine.

Please read this leaflet carefully before taking Fampridine 10 mg Ascend.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- **Fampridine 10 mg Ascend** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What **Fampridine 10 mg Ascend** is and what it is used for
2. What you need to know before you take **Fampridine 10 mg Ascend**
3. How to take **Fampridine 10 mg Ascend**
4. Possible side effects
5. How to store **Fampridine 10 mg Ascend**
6. Contents of the pack and other information

1. WHAT FAMPRIDINE 10 MG ASCEND IS AND WHAT IT IS USED FOR

Fampridine 10 mg Ascend contains the active substance fampridine which belongs to a group of medicines called potassium channel blockers. They work by stopping potassium leaving the nerve cells which have been damaged by MS. This medicine is thought to work by letting signals pass down the nerve more normally, which allows you to walk better.

Fampridine 10 mg Ascend is a medicine used to improve walking in adults with Multiple Sclerosis (MS) related walking disability. In multiple sclerosis, inflammation destroys the

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protective sheath around the nerves leading to muscle weakness, muscle stiffness and difficulty walking.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FAMPRIDINE 10 MG ASCEND

Do not take Fampridine 10 mg Ascend if:

- You are allergic to fampridine or any of the other ingredients of this medicine (listed in section 6.1).
- if you are taking any other medicine containing fampridine. This may increase your risk of serious side effects
- if you have a seizure or have ever had a seizure (also referred to as a fit or convulsion)
- if your doctor or nurse has told you that you have moderate or severe kidney problems
- if you are taking a medicine called cimetidine (medicine used to treat ulcers)

Do not take Fampridine 10 mg Ascend if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking **Fampridine 10 mg Ascend**.

Warnings and special precautions:

Take special care with Fampridine 10 mg Ascend:

- if you feel aware of your heartbeat (*palpitations*)
- if you are prone to infections
- if you have any factors or are taking any medicine which affects your risk of fits (*seizure*).
- if you have been told by a doctor that you have mild problems with your kidneys
- if you have history of allergic reactions

You should use a walking aid, such as a cane, as needed because this medicine may make you feel dizzy or unsteady this may result in an increased risk of falls.

Children and adolescents

The use of **Fampridine 10 mg Ascend** is not recommended in children under the age of 18.

Elderly

Before starting treatment and during treatment your doctor may check that your kidneys are working properly.

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Using other medicines with Fampridine 10 mg Ascend:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Do not take Fampridine 10 mg Ascend if you are taking any other medicine containing fampridine or cimetidine.

Tell your doctor especially if you are taking any medicines that affect the kidneys.

Your doctor will be especially careful if fampridine is given at the same time as any medicine which may affect how your kidneys eliminate medicines for example carvedilol, propranolol and metformin.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Pregnancy and Breastfeeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. It is better not to use this medicine when you are pregnant.

You should not breast-feed whilst taking this medicine.

Driving and using machines

Fampridine 10 mg Ascend may have an effect on people's ability to drive or use machines, it can cause dizziness. Make sure you are not affected before you start driving or use machinery.

3. HOW TO TAKE FAMPRIDINE 10 MG ASCEND

Do not share medicines prescribed for you with any other person.

Always take **Fampridine 10 mg Ascend** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Fampridine 10 mg Ascend is only available by prescription and under the supervision of doctors experienced in MS.

Your doctor will give you an initial prescription for 2 to 4 weeks. After 2 to 4 weeks the treatment will be reassessed.

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The recommended starting dose is **One** tablet in the morning and **one** tablet in the evening (12 hours apart). Do not take more than two tablets in a day.

You must leave 12 hours between each tablet. Do not take the tablets more often than every 12 hours.

Fampridine 10 mg Ascend is for oral use. **Swallow each tablet whole**, with a drink of water. Do not divide, crush, dissolve, suck or chew the tablet.

This medicine should be taken without food, on an empty stomach.

Children:

Not to be given to children under the age of 18.

If you take more Fampridine 10 mg Ascend than you should:

Contact your doctor immediately if you take too many tablets. If possible, take your tablets or the box with you to show the doctor.

Taking too many tablets may cause sweating, minor shaking (*tremor*), dizziness, confusion, memory loss (*amnesia*) and fits (*seizure*). You may also notice other effects not listed here.

If you forget to take Fampridine 10 mg Ascend:

If you forget to take a dose, take them as soon as you remember. Wait 12 hours before next dose. Never double up on a dose to make up for the one you have missed.

4. POSSIBLE SIDE EFFECTS

Fampridine 10 mg Ascend can have side effects.

Not all side effects reported for FAMPRIDINE 10 MG ASCEND are included in this leaflet.

Should your general health worsen while taking **Fampridine 10 mg Ascend** please consult your doctor, pharmacist, or other healthcare professional for advice.

If any of the following happens, stop taking **Fampridine 10 mg Ascend** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swollen face, mouth, lips, throat or tongue,
- reddening or itching of the skin,
- chest tightness and breathing problems.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

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Frequent side-effects:

- Urinary tract infection
- Feeling unsteady
- Dizziness
- Spinning sensation (*vertigo*)
- Headache
- Feeling weak and tired
- Difficulty sleeping
- Anxiety
- Minor shaking (*tremor*)
- Numbness or tingling of skin
- Sore throat
- Common cold (*nasopharyngitis*)
- Flu (*influenza*)
- Viral infection
- Difficulty breathing (shortness of breath)
- Feeling sick (*nausea*)
- Being sick (*vomiting*)
- Constipation
- Upset stomach
- Back pain
- Heartbeat that you can feel (*palpitations*)

Less frequent side-effects:

- Fits (*seizure*)
- Allergic reaction (*hypersensitivity*)
- Severe allergy (*anaphylactic reaction*)
- Swelling of the face, lips, mouth or tongue (*angioedema*)
- New onset or worsening of nerve pain in the face (*trigeminal neuralgia*)
- Fast heart rate (*tachycardia*)
- Dizziness or loss of consciousness (*hypotension*)
- Rash/itchy rash (*urticaria*)
- Chest discomfort

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If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **Fampridine 10 mg Ascend**. All adverse events must also be reported to Ascend Laboratories via the e-mail: pharmacist.rsa@Alkem.com.

5. HOW TO STORE FAMPRIDINE 10 MG ASCEND

Store at or below 25 °C.

Keep bottle tightly closed. Keep blisters in carton.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date stated on the carton.

Do not throw away any medicines in drains or sewage systems.

Return all unused medicine to the pharmacist.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

The active ingredient is fampridine.

Tablet core: Colloidal silicon dioxide, hydroxypropyl methylcellulose (hypromellose), magnesium stearate, microcrystalline cellulose,

Film coating (Opadry Y-1-7000H White): hypromellose (E464), macrogol (E1521), titanium dioxide (E171)

What Fampridine 10 mg Ascend looks like and contents of the pack:

White to off white biconvex, oval shaped, bevelled edge, film coated tablets, debossed "D10" on one side and plain on other side.

Contents of the pack:

Fampridine 10 mg Ascend is packed in white, high-density polyethylene (HDPE) bottles with child resistant cap containing 60 tablets, as well as in Aluminium-aluminium blister strips of 10 tablets each.

The strips are packed in pack sizes of 10 (1x 10's), 30 (3 x 10's) and 60 (6 x 10's) tablets in a printed cardboard carton.

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Holder of certificate of registration

Ascend Laboratories (Pty) Ltd.

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This leaflet was last revised in

2 June 2026

Application Numbers:

590869

Access to the corresponding Professional Information

The professional information will be included in each unit pack of the product.