

**B. PACKAGE LEAFLET**

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### FIRDAPSE 10 mg tablets

amifampridine

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your doctor or pharmacist.

This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

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

#### 1. What FIRDAPSE is and what is it used for

FIRDAPSE is used to treat symptoms of a disease of the nerves and the muscles called Lambert-Eaton myasthenic syndrome or LEMS in adults. This disease is a disorder affecting the transmission of nerve impulses to muscles, resulting in muscle weakness. It can be associated with certain tumour types (paraneoplastic form of LEMS) or in the absence of these tumours (non-paraneoplastic form of LEMS).

In patients suffering from this disease, a chemical substance called acetylcholine, which communicates nerve impulses to muscles is not released normally and the muscle doesn't receive some or all of the nerve's signals.

FIRDAPSE works by increasing the release of acetylcholine and helps the muscle to receive the nerve signals.

#### 2. What you need to know before you take FIRDAPSE

##### Do not take FIRDAPSE

If you are allergic to amifampridine, or any of the other ingredients of this medicine (listed in section 6)

If you have uncontrolled asthma

If you are epileptic

Together with medicines that may change the electrical activity of your heart (QT-interval prolongation - detectable in the electrocardiogram), such as:

Sultropride (a medicine prescribed to treat certain behavioural disorders in adults),

Antiarrhythmic medicine (e.g., disopyramide)

Medicines to treat digestive problems (e.g., cisapride, domperidone)

Medicines to treat infections - antibiotics (e.g., rifampicin) and antifungals (e.g., ketoconazole)  
Together with medicines with a therapeutic dose close to the maximum safe dose  
If you were born with heart problems (congenital QT syndromes)

If you have any doubts, ask your doctor or pharmacist for advice.

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking FIRDAPSE.

Tell your doctor if you have  
Asthma  
A history of fits (convulsions)  
Kidney problems  
Liver problems

Your doctor will monitor carefully how FIRDAPSE works for you and may need to change the dose of the medicines you take. Your doctor will also monitor your heart at the start of your treatment and also every year thereafter.

If you have LEMS but do not have cancer, your doctor will make a thorough assessment of the potential risk of cancer with FIRDAPSE before commencing treatment.

Tell any physician you consult that you are using FIRDAPSE.

### **Stop the treatment and immediately consult your doctor in the event of:**

Fits (convulsions)  
Asthma

### **Other medicines and FIRDAPSE**

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Some medicines may interact with FIRDAPSE when taken together. The following medicines must not be combined with FIRDAPSE:

Medicines that may change the electrical activity of your heart (QT-interval prolongation - detectable in the electrocardiogram) e.g., sultopride, disopyramide, cisapride, domperidone, rifampicin, and ketoconazole (see "Do not take FIRDAPSE")

It is especially important to talk to your doctor if you are taking one of the following medicines or plan to start taking the following medicines:

Medicines for malaria (e.g. halofantrine and mefloquine)

Tramadol (a painkiller)

Antidepressants - tricyclic antidepressants (e.g. clomipramine, amoxapine), selective serotonin reuptake inhibitors (e.g. citalopram, dapoxetine) and atypical antidepressants (e.g. bupropion)

Medicines for mental problems (e.g. haloperidol, carbamazepine, chlorpromazine, clozapine)

Medicines to treat Parkinson's disease - anticholinergics (e.g. trihexyphenidyl, mesylate), MAO-B inhibitors (e.g. selegiline, deprenyl), COMT inhibitors (e.g. entacapone)

Medicines to treat allergies - antihistamines (e.g. terfenadine, astemizole, cimetidine)

Medicines to relax your muscles - (e.g. mivacurium, pipercurium, suxamethonium)

Sedatives (e.g. barbiturates)

### **Pregnancy and breast-feeding**

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.

FIRDAPSE should not be used if you are pregnant. You must use effective contraception throughout the treatment. If you discover that you are pregnant during the treatment, inform your doctor immediately.

It is not known whether FIRDAPSE is excreted in human breast milk. You and your doctor should discuss the risks and benefits of continuing to take FIRDAPSE while breastfeeding.

### **Driving and using machines**

This medicine may cause drowsiness, dizziness, fits (convulsions) and blurred vision, which may affect your ability to drive or use machines. Do not drive or operate machines if you experience these side effects.

## **3. How to take FIRDAPSE**

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The dose you should take is established by your doctor based on the intensity of your symptoms and certain genetic factors. This dose suits you only.

The starting dose is 5 mg amifampridine (half a tablet) three times daily (i.e. 15 mg per day). Your doctor may increase this dose slowly first to 5 mg (half a tablet) four times daily (i.e. 20 mg per day). Then your doctor may continue to increase your total daily dose adding 5 mg (half a tablet) per day, every 4 or 5 days.

The maximum recommended dose is 60 mg per day (i.e. a total of six tablets to be taken at intervals during the day). Total daily doses above 20 mg should be divided into two to four separate doses. No single dose should exceed 20 mg (two tablets).

The tablets have a score-line to allow them to be broken in half. The tablets should be swallowed with some water and are to be taken with food.

### **Patients with liver/kidney problems:**

FIRDAPSE should be used with caution in patients with liver or kidney problems. A starting dose of 5 mg (half tablet) FIRDAPSE daily is recommended in patients with moderate or severe liver or kidney problems. For patients with mild liver or kidney problems a starting dose of 10 mg (5 mg twice a day) FIRDAPSE daily is recommended. For these patients the dose of FIRDAPSE should be increased more slowly than in those without liver or kidney problems with doses increased in 5 mg increments every 7 days. If any side effects occur, please consult your doctor as you may need to stop increasing the dose.

### **If you take more FIRDAPSE than you should**

If you take more FIRDAPSE than you should have, you may suffer from vomiting or a stomach ache. If you experience any of these symptoms, you should contact your doctor or pharmacist immediately.

### **If you forget to take FIRDAPSE**

If you forget to take FIRDAPSE, do not take a double dose to make up for the dose you have forgotten but continue to take your treatment as prescribed by your doctor.

### **If you stop taking FIRDAPSE**

If the treatment is stopped, you may experience symptoms such as tiredness, slow reflexes and constipation. Do not stop treatment without consulting your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

##### **Stop the treatment and immediately consult your doctor in the event of:**

Fits (convulsions)

Asthma

##### **Very common side effects which may affect more than 1 in 10 people are:**

Tingling and numbness around the mouth and extremities (such as feet and hands)

Reduced sense of touch or sensation

Nausea

Dizziness

Increase sweating, cold sweat

##### **Common side effects which may affect up to 1 in 10 people are:**

Stomach ache

Cold hands and feet

##### **Other side effects are:**

The intensity and incidence of most side effects depends on the dose you are taking. The following side effects have also been reported (frequencies cannot be estimated from the available data):

Raynaud's syndrome (circulation disorder affecting the fingers and toes)

Diarrhoea

Fits (convulsions)

Cough, excessive or viscous mucus in the breathing passage, asthma attack in asthmatic patients or patients with a history of asthma

Blurred vision

Heart rhythm disorders, fast or irregular heartbeats (palpitations)

Weakness, tiredness, headache

Anxiety, sleep disorders, drowsiness

Chorea (movement disorder), myoclonia (muscle spasm or twitching)

Increase in certain liver enzymes (transaminases) seen on blood tests

##### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. How to store FIRDAPSE**

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

Do not use this medicine after the expiry date which is stated on the packaging after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C. Store in the original package, in order to protect from light and moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## **6. Contents of the pack and other information**

### **What FIRDAPSE contains**

The active substance is amifampridine. Each tablet contains amifampridine phosphate equivalent to 10 mg of amifampridine.

The other ingredients are microcrystalline cellulose, anhydrous colloidal silica and calcium stearate.

### **What FIRDAPSE looks like and contents of the pack**

White, round tablet, flat-faced on one side and scored on the other side.

The tablets can be divided into equal halves.

Perforated unit dose thermoformed blisters (Thermoformed aluminium-PVC/PVDC laminate sheets) containing 10 tablets.

One box contains 100 tablets comprising 10 strips with 10 tablets each.

### **Marketing Authorisation Holder**

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### **Manufacturers**

EXCELLA GmbH & Co KG

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