

10 mg extended-release tablet

Read this entire leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

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

1. What Pyralock® is and what it is used for

Fampridine, the active substance of Pyralock®, 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.

Pyralock® is a medicine used to improve walking in adults (18 years and over) with Multiple Sclerosis (MS) related walking disability. In multiple sclerosis, inflammation destroys the protective sheath around the nerves leading to muscle weakness, muscle stiffness and difficulty walking.

2. What you need to know before you are given Pyralock®**Do not take Pyralock®:**

- if you are allergic to Fampridine or any of the other ingredients of this medicine (listed in section 6)
- 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
- if you are taking any other medicine containing Fampridine. This may increase your risk of serious side effects

Tell your doctor and do not take Pyralock® if any of these apply to you.

Warnings and precautions

Talk to your doctor or pharmacist before taking Pyralock®:

- 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.

Tell your doctor before you take Pyralock® if any of these apply to you.

Children and adolescents

Do not give this medicine to children or adolescents under the age of 18 years.

Elderly

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

Other medicines and Pyralock®

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

Do not take Pyralock® if you are taking any other medicine containing Fampridine.**Other medicines that affect the kidneys**

Your doctor will be especially careful if Pyralock® is given at the same time as any medicine which may affect how your kidneys eliminate medicines.

Avoid taking Pyralock® with the following medicines:

- Dolutegravir might increase the concentration of fampridine.
- H₂ receptor antagonists (cimetidine) increase the concentration of fampridine.

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.

Pyralock® is not recommended during pregnancy.

Your doctor will consider the benefit of you being treated with Pyralock® against the risk to your baby.

You should not breast-feed whilst taking this medicine.

Driving and using machines

Pyralock® 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 Pyralock® is used

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Pyralock® 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. The recommended 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.

Pyralock® is for oral use.

Swallow each tablet whole, with a drink of water. Do not divide, crush, dissolve, suck or chew the tablet. This may increase your risk of side effects.

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

If you take more Pyralock® than you should

Contact your doctor immediately if you take too many tablets. Take the Pyralock® box with you if you go to see the doctor. In overdose you may notice 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 Pyralock®

If you forget to take a tablet, do not take two tablets at once to make up for a missed dose. You must always leave 12 hours between each tablet.

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

4. Possible side effects

If you have a seizure, stop taking Pyralock® and tell your doctor immediately.

If you experience one or more of the following allergic (hypersensitivity) symptoms: swollen face, mouth, lips, throat or tongue, reddening or itching of the skin, chest tightness and breathing problems stop taking Pyralock® and see your doctor immediately.

Common or very common

Anxiety, asthenia, balance impaired, constipation, dizziness, dyspepsia, dyspnea, headache, insomnia, laryngeal pain, nausea, pain, palpitations, paresthesia, tremor, urinary tract infection, vomiting, feeling unsteady, feeling weak and tired, numbness or tingling of skin, sore throat, common cold (nasopharyngitis), flu (influenza), viral infection, upset stomach, back pain

Uncommon

Seizure, skin reactions, tachycardia, 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), dizziness or loss of consciousness (hypotension), rash/itchy rash (urticaria)

5. How to store Pyralock®

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 package after EXP. The expiry date refers to the last day of that month.

Store below 30 °C.

Store the tablets in the original package in order to protect from light and moisture.

Do not throw away any medicines via waste water 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 Pyralock® contains**

- The active substance is fampridine.

Each extended-release tablet contains 10 mg of fampridine

- The other ingredients are:

Hydroxypropyl methyl cellulose (K100), microcrystalline cellulose, silica colloidal anhydrous, magnesium stearate

What Pyralock® looks like and contents of the pack

Pyralock® is a round, yellow, film coated, extended-release tablet with breakline on one side.

Each bottle contains 60 extended-release tablets.

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 Sobhan Oncology Co.	
Leaflet	Pyralock®
Color	PANTONE 295 U 
Size	120 mm x 250 mm Tolerance: 1±mm
Grammage	58-72 g/m²
File Name	FMBT-0000-LF-00
date	21.07.04