LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Lyribastad
(pregabalin)

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Summary Public Assessment Report

Lyribastad
(pregabalin)

Capsule hard, 25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg, 300mg

This is a summary of the public assessment report (PAR) for Lyribastad. It explains how Lyribastad was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Lyribastad.

For practical information about using Lyribastad, patients should read the package leaflet or contact their doctor or pharmacist.

What is Lyribastad and what is it used for?

Lyribastad is a 'generic medicine'. This means that Lyribastad is similar to a 'reference medicine' already authorised in the European Union (EU) called Lyrica.

Lyribastad is used to treat:

Peripheral and central neuropathic pain: Long lasting pain caused by damage to the nerves. A variety of diseases can cause peripheral neuropathic pain, such as diabetes or shingles. Pain sensations may be described as hot, burning, throbbing, shooting, stabbing, sharp, cramping, aching, tingling, numbness, pins and needles. Peripheral and central neuropathic pain may also be associated with mood changes, sleep disturbance, fatigue (tiredness), and can have an impact on physical and social functioning and overall quality of life.

Epilepsy: A certain form of epilepsy (partial seizures with or without secondary generalisation) in adults. Your doctor will prescribe Lyribastad for you to help treat your epilepsy when your current treatment is not controlling your condition. You should take Lyribastad in addition to your current treatment. Lyribastad is not intended to be used alone, but should always be used in combination with other anti-epileptic treatment.

Generalised Anxiety Disorder: The symptoms of GAD are prolonged excessive anxiety and worry that are difficult to control. GAD can also cause restlessness or feeling keyed up or on edge, being easily fatigued (tired), having difficulty concentrating or mind going blank, feeling irritable, having muscle tension or sleep disturbance. This is different to the stresses and strains of everyday life.

How does Lyribastad work?

The active substance pregabalin belongs to a group of medicines used to treat epilepsy, neuropathic pain and Generalised Anxiety Disorder (GAD) in adults.

How is Lyribastad used?

The pharmaceutical form of Lyribastad is capsule, hard for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Lyribastad have been shown in studies?

Because Lyribastad is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Lyrica. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Lyribastad?

Because Lyribastad is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine. For the full list of restrictions, see the package leaflet.

Why is Lyribastad approved?

It was concluded that, in accordance with EU requirements, Lyribastad has been shown to have comparable quality and to be bioequivalent to the reference medicine Lyrica. Therefore, the Medical Products Agency in Sweden decided that, as for Lyrica, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Lyribastad?

A risk management plan has been developed to ensure that Lyribastad is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Lyribastad, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Lyribastad

The marketing authorisation for Lyribastad was granted on 2017-12-15 in Sweden.

The full PAR for Lyribastad can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Lyribastad, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2018-01.