



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## EPAR summary for the public

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# Lyrica

pregabalin

This document is a summary of the European Public Assessment Report (EPAR) for Lyrica. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Lyrica.

## What is Lyrica?

Lyrica is a medicine that contains the active substance pregabalin. It is available as capsules (white: 25, 50 and 150 mg; white and orange: 75, 225 and 300 mg; orange: 100 mg; light orange: 200 mg) and as an oral solution (20 mg/ml).

## What is Lyrica used for?

Lyrica is used to treat adults with the following conditions:

- neuropathic pain (pain due to nerve damage). Lyrica can be used in peripheral neuropathic pain, such as the pain experienced by diabetic patients or by patients who have had herpes zoster (shingles), and central neuropathic pain, such as the pain experienced by patients who have had a spinal cord injury;
- epilepsy. Lyrica is used as an 'add-on' to existing treatment in patients who have partial seizures (epileptic fits starting in one specific part of the brain) that cannot be controlled with their current treatment;
- generalised anxiety disorder (long-term anxiety or nervousness about everyday matters).

The medicine can only be obtained with a prescription.



## How is Lyrica used?

The recommended starting dose of Lyrica is 150 mg per day, divided into two or three doses. After three to seven days, the dose can be increased to 300 mg per day. Doses can be increased up to twice more until the most effective dose is reached. The maximum dose is 600 mg per day. Stopping treatment with Lyrica should also be done gradually, over at least a week.

The capsules should be swallowed whole with water. Patients who have kidney problems need to take lower doses.

## How does Lyrica work?

The active substance in Lyrica, pregabalin, is similar in structure to the body's own 'neurotransmitter' gamma-aminobutyric acid (GABA), but has very different biological effects. Neurotransmitters are chemicals that allow nerve cells to communicate with each other. The exact way that pregabalin works is not fully understood, but it is thought to affect the way that calcium enters nerve cells. This reduces the activity of some of the nerve cells in the brain and spinal cord, reducing the release of other neurotransmitters that are involved in pain, epilepsy and anxiety.

## How has Lyrica been studied?

Lyrica has been compared with placebo (a dummy treatment) in 22 studies:

- for peripheral neuropathic pain, there were ten studies involving over 3,000 patients, about half of whom had diabetic neuropathy and half of whom had pain following shingles. A further study was carried out in 137 patients with central neuropathic pain due to a spinal cord injury. The studies lasted up to 12 weeks. The effectiveness of Lyrica was measured using a standard pain questionnaire;
- for epilepsy, there were three studies involving over 1,000 patients. The main measure of effectiveness was the change in the number of seizures after 11 to 12 weeks;
- for generalised anxiety disorder, there were eight studies involving over 3,000 patients. Effectiveness was measured using a standard anxiety questionnaire after four to eight weeks.

## What benefit has Lyrica shown during the studies?

In neuropathic pain, Lyrica was more effective than placebo in decreasing pain. In peripheral neuropathic pain, 35% of the patients treated with Lyrica had a decrease in pain scores of 50% or more, compared with 18% of the patients treated with placebo. In central neuropathic pain, 22% of patients treated with Lyrica had a decrease in pain scores of 50% or more, compared with 8% of the patients treated with placebo.

In epilepsy, Lyrica reduced the number of seizures: about 45% of the patients taking 600 mg Lyrica a day and about 35% of those taking 300 mg Lyrica a day had a reduction in seizures of 50% or more. This compared with about 10% of the patients taking placebo.

In generalised anxiety disorder, Lyrica was more effective than placebo: 52% of the patients taking Lyrica had an improvement of 50% or more, compared with 38% of the patients taking placebo.

## **What is the risk associated with Lyrica?**

The most common side effects with Lyrica (seen in more than 1 patient in 10) are dizziness and somnolence (sleepiness). For the full list of all side effects reported with Lyrica, see the Package Leaflet.

Lyrica should not be used in people who may be hypersensitive (allergic) to pregabalin or any of the other ingredients.

## **Why has Lyrica been approved?**

The CHMP decided that Lyrica's benefits are greater than its risks and recommended that it be given marketing authorisation.

## **Other information about Lyrica:**

The European Commission granted a marketing authorisation valid throughout the European Union for Lyrica to Pfizer Limited on 6 July 2004. The marketing authorisation is valid for an unlimited period.

The full EPAR for Lyrica can be found [here](#). For more information about treatment with Lyrica, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 04-2010.