



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/220635/2014  
EMA/H/C/003880

## EPAR summary for the public

---

# Pregabalin Pfizer

## pregabalin

This is a summary of the European public assessment report (EPAR) for Pregabalin Pfizer. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Pregabalin Pfizer.

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

### What is Pregabalin Pfizer and what is it used for?

Pregabalin Pfizer is a medicine that contains the active substance pregabalin. It is used to treat adults with the following conditions:

- neuropathic pain (pain due to nerve damage), including peripheral neuropathic pain, such as the pain experienced by patients with diabetes or herpes zoster (shingles), and central neuropathic pain, such as the pain experienced by patients who have had a spinal cord injury;
- epilepsy, where it 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).

This medicine is the same as Lyrica, which is already authorised in the European Union (EU). The company that makes Lyrica has agreed that its scientific data can be used for Pregabalin Pfizer ('informed consent').

### How is Pregabalin Pfizer used?

The medicine can only be obtained with a prescription and is available as capsules (25, 50, 75, 100, 150, 200, 225 and 300 mg). The recommended starting dose of Pregabalin Pfizer 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 Pregabalin Pfizer 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 Pregabalin Pfizer work?**

The active substance in Pregabalin Pfizer, pregabalin, is similar in structure to the body's own 'neurotransmitter' gamma-amino butyric 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.

## **What benefits of Pregabalin Pfizer have been shown in studies?**

Pregabalin Pfizer has been compared with placebo (a dummy treatment) in 22 studies.

In neuropathic pain, the benefits of Pregabalin Pfizer were evaluated for up to 12 weeks using a standard pain questionnaire. In 10 studies involving over 3,000 patients with peripheral neuropathic pain (either diabetic pain or shingles), 35% of the patients treated with Pregabalin Pfizer had a decrease in pain scores of 50% or more, compared with 18% of the patients treated with placebo. In a smaller study involving 137 patients with central neuropathic pain due to a spinal cord injury, 22% of patients treated with Pregabalin Pfizer had a decrease in pain scores of 50% or more, compared with 8% of the patients treated with placebo.

In epilepsy, the benefits of Pregabalin Pfizer were evaluated in 3 studies involving 1,000 patients that looked at how much it reduced the number of seizures patients had after 11 to 12 weeks. About 45% of the patients taking 600 mg Pregabalin Pfizer a day and about 35% of those taking 300 mg Pregabalin Pfizer a day had a reduction in seizures of 50% or more. This compared with about 10% of the patients taking placebo.

Pregabalin Pfizer was more effective than placebo in generalised anxiety disorder: in 8 studies involving over 3,000 patients, 52% of the patients taking Pregabalin Pfizer had an improvement of 50% or more in their anxiety measured with a standard anxiety questionnaire, compared with 38% of the patients taking placebo.

## **What are the risks associated with Pregabalin Pfizer?**

The most common side effects with Pregabalin Pfizer (seen in more than 1 patient in 10) are dizziness and somnolence (sleepiness). For the full list of all side effects and restrictions, see the package leaflet.

## **Why is Pregabalin Pfizer approved?**

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

## **What measures are being taken to ensure the safe and effective use of Pregabalin Pfizer?**

A risk management plan has been developed to ensure that Pregabalin Pfizer 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 Pregabalin Pfizer, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the summary of the risk management plan.

## **Other information about Pregabalin Pfizer**

The European Commission granted a marketing authorisation valid throughout the European Union for Pregabalin Pfizer on 10 April 2014.

The full EPAR and risk management plan summary for Pregabalin Pfizer can be found on the Agency's website: [ema.europa.eu/Find\\_medicine/Human\\_medicines/European\\_public\\_assessment\\_reports](http://ema.europa.eu/Find_medicine/Human_medicines/European_public_assessment_reports). For more information about treatment with Pregabalin Pfizer, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 04-2014.