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Pregabalin Viatris Pharma[1] (*pregabalin*)

An overview of Pregabalin Viatris Pharma and why it is authorised in the EU

What is Pregabalin Viatris Pharma and what is it used for?

Pregabalin Viatris Pharma is a medicine 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 other epilepsy treatment in patients who have partial seizures (epileptic fits starting in one specific part of the brain);
- 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 Viatris Pharma ('informed consent').

How is Pregabalin Viatris Pharma used?

Pregabalin Viatris Pharma is available as capsules and can only be obtained with a prescription. The recommended starting dose is divided into two or three doses. After three to seven days, the dose can be increased. Doses can be increased further until the most effective dose is reached. To stop treatment with Pregabalin Viatris Pharma the dose should be reduced gradually, over at least a week. Patients who have kidney problems may need to take lower doses.

For more information about using Pregabalin Viatris Pharma, see the package leaflet or contact your doctor or pharmacist.

How does Pregabalin Viatris Pharma work?

The active substance in Pregabalin Viatris Pharma, pregabalin, is similar in structure to the body's own 'neurotransmitter' gamma-amino butyric acid (GABA), but has very different biological effects.

[1] Previously known as Pregabalin Pfizer.

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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 epilepsy and anxiety.

What benefits of Pregabalin Viatris Pharma have been shown in studies?

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

In neuropathic pain, the benefits of Pregabalin Viatris Pharma 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 Viatris Pharma 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 Viatris Pharma 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 Viatris Pharma 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 Viatris Pharma a day and about 35% of those taking 300 mg Pregabalin Viatris Pharma a day had a reduction in seizures of 50% or more. This compared with about 10% of the patients taking placebo.

Pregabalin Viatris Pharma was more effective than placebo in generalised anxiety disorder: in 8 studies involving over 3,000 patients, 52% of the patients taking Pregabalin Viatris Pharma 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 Viatris Pharma?

For the full list of side effects and restrictions with Pregabalin Viatris Pharma, see the package leaflet.

The most common side effects with Pregabalin Viatris Pharma (seen in more than 1 patient in 10) are dizziness and somnolence (sleepiness).

Why is Pregabalin Viatris Pharma authorised in the EU?

The European Medicines Agency decided that Pregabalin Viatris Pharma’s benefits are greater than its risks and that it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Pregabalin Viatris Pharma?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Pregabalin Viatris Pharma have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Pregabalin Viatris Pharma are continuously monitored. Suspected side effects reported with Pregabalin Viatris Pharma are carefully evaluated and any necessary action taken to protect patients.

Other information about Pregabalin Viatris Pharma

Pregabalin Pfizer received a marketing authorisation valid throughout the EU on 25 June 2015.

The name of the medicine was changed to Pregabalin Viatris Pharma on 7 April 2025.

Further information on Pregabalin Viatris Pharma can be found on the Agency's website: www.ema.europa.eu/medicines/human/EPAR/pregabalin-viatris-pharma.

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