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Pregabalin Viatris[1] (*pregabalin*)

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

What is Pregabalin Viatris and what is it used for?

Pregabalin Viatris 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).

Pregabalin Viatris contains the active substance pregabalin and is a 'generic medicine'. This means that Pregabalin Viatris contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU. The reference medicine for Pregabalin Viatris is Lyrica. For more information on generic medicines, see the question-and-answer document here.

How is Pregabalin Viatris used?

Pregabalin Viatris is available as capsules to be taken by mouth and can only be obtained with a prescription.

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

How does Pregabalin Viatris work?

The active substance in Pregabalin Viatris, 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

[1] Previously known as Pregabalin Viatris.

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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.

How has Pregabalin Viatris been studied?

Studies on the benefits and risks of the active substance in the approved uses have already been carried out with the reference medicine, Lyrica, and do not need to be repeated for Pregabalin Viatris.

As for every medicine, the company provided studies on the quality of Pregabalin Viatris. The company also carried out studies that showed that it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

What are the benefits and risks of Pregabalin Viatris?

Because Pregabalin Viatris is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Pregabalin Viatris authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Pregabalin Viatris has been shown to have comparable quality and to be bioequivalent to Lyrica. Therefore, the Agency's view was that, as for Lyrica, the benefits of Pregabalin Viatris outweigh the identified risks and it can be authorised for use in the EU.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Pregabalin Viatris have been included in the summary of product characteristics and the package leaflet. Any additional measures in place for Lyrica also apply to Pregabalin Viatris where appropriate.

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

Other information about Pregabalin Viatris

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

The name of the medicine was changed to Pregabalin Viatris on 24 July 2024.

Further information on Pregabalin Viatris can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/pregabalin-viatris. Information on the reference medicine can also be found on the Agency's website.

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