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Paxneury (*guanfacine*)

An overview of Paxneury and why it is authorised in the EU

What is Paxneury and what is it used for?

Paxneury is used to treat attention deficit hyperactivity disorder (ADHD) in children and adolescents aged 6 to 17 years when stimulant medicines are not appropriate or do not control their symptoms well enough.

Paxneury is used as part of a comprehensive treatment programme that typically involves psychological, educational and other interventions.

Paxneury contains the active substance guanfacine and is a 'hybrid' and a 'generic' medicine. This means that it is similar to a 'reference medicine' containing the same active substance, but there are certain differences between the two. The reference medicine for Paxneury is Intuniv. Paxneury is available in the same strengths as Intuniv (1, 2, 3 and 4 mg) as well as in the additional strengths 4,5 and 7 mg.

How is Paxneury used?

Paxneury treatment must be started by a doctor specialised in childhood or adolescent behavioural problems. Before starting treatment, the doctor should carry out checks to see whether the patient is at risk of side effects of the medicine (particularly sleepiness, effects on heart rate and blood pressure, and weight gain).

The dose of Paxneury requires careful adjustments, taking into account side effects and benefits seen in the patient. Weekly monitoring for signs and symptoms of sleepiness and effects on heart rate and blood pressure is required at the start of treatment and the patient should continue to be monitored at least every 3 months for the first year. Six-monthly monitoring is required thereafter, with more frequent monitoring following any dose adjustment.

The recommended starting dose for all patients is 1 mg taken by mouth once a day which is increased to a maintenance dose based on body weight according to the patient's response and tolerability. The medicine can only be obtained with a prescription.

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

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How does Paxneury work?

The way Paxneury works in ADHD is not established. It is thought that the active substance, guanfacine, might influence the way signals are transmitted between cells in areas of the brain called the prefrontal cortex and basal ganglia by attaching to certain receptors that are heavily concentrated in these areas.

How has Paxneury been studied?

Studies on the benefits and risks of the active substance in the authorised use have already been carried out with the reference medicine, Intuniv, and do not need to be repeated for Paxneury.

As for every medicine, the company provided studies on the quality of Paxneury. 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 Paxneury?

Because Paxneury 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 Paxneury authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Paxneury has been shown to have comparable quality and to be bioequivalent to the reference medicine. Therefore, the Agency's view was that, as for the reference medicine, the benefits of Paxneury 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 Paxneury?

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

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

Other information about Paxneury

Paxneury received a marketing authorisation valid throughout the EU on 26 February 2025

Further information on Paxneury can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/paxneury

Information on the reference medicine can also be found on the Agency's website.

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