12 December 2024
EMA/CHMP/575645/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Paxneury

guanfacine

On 12 December 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Paxneury, intended for the treatment of attention deficit hyperactivity disorder in children.

The applicant for this medicinal product is Neuraxpharm Pharmaceuticals S.L.

Paxneury will be available as 1 mg, 2 mg, 3 mg, 4 mg, 5 mg, 6 mg and 7 mg prolonged-release tablets. The active substance of Paxneury is guanfacine hydrochloride, a centrally acting antiadrenergic agent (ATC code: C02AC02). Guanfacine is a selective alpha$_{2A}$-adrenergic receptor agonist which is expected to work by modulating the signalling pathways in the brain that are thought to be responsible for the symptoms of ADHD.

Paxneury 1 mg, 2 mg, 3 mg and 4 mg is a generic of Intuniv, which has been authorised in the EU since 17 September 2015. A question and answer document on generic medicines can be found here.

Paxneury 5 mg, 6 mg and 7 mg is a hybrid medicine[2] of Intuniv. Paxneury contains the same active substance as Intuniv, but is available at higher strengths.

Studies have demonstrated the satisfactory quality of Paxneury and its bioequivalence to the reference product Intuniv.

The benefits of Paxneury are expected to be comparable to that of the reference medicine, Intuniv; it reduces the behavioural symptoms of ADHD, mainly hyperactivity, impulsivity, short attention span and distractibility. The most common side effects with Paxneury are somnolence, headache, fatigue, abdominal pain and sedation. The most common serious side effects with Paxneury are hypotension, weight increase, bradycardia and syncope.

The full indication is:

> Paxneury is indicated for the treatment of attention deficit hyperactivity disorder (ADHD) in

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.
[2] Hybrid applications rely in part on the results of pre-clinical tests and clinical trials for a reference product and in part on new data.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

children and adolescents 6-17 years old for whom stimulants are not suitable, not tolerated or have been shown to be ineffective.

Paxneury must be used as a part of a comprehensive ADHD treatment programme, typically including psychological, educational and social measures.

Treatment with Paxneury must be initiated under the supervision of an appropriate specialist in childhood and/or adolescent behavioural disorders.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.