12 December 2024
EMA/CHMP/574129/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Tuzulby

methylphenidate

On 12 December 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a paediatric use marketing authorisation (PUMA) for the medicinal product Tuzulby, intended for the treatment of children with attention-deficit hyperactivity disorder (ADHD).

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

Tuzulby will be available as 20 mg, 30 mg and 40 mg modified-release chewable tablets. The active substance of Tuzulby is methylphenidate hydrochloride, a psychostimulant agent used for ADHD (ATC code: N06BA04). Methylphenidate is thought to work by inhibiting dopamine reuptake in the brain without triggering dopamine release.

Tuzulby is a hybrid medicine[2] of Ritalin, which has been authorised in the EU since 15 January 1997. Tuzulby contains the same active substance as Ritalin, but is available in a different formulation and strength, and is given once daily. Studies have demonstrated the satisfactory quality of Tuzulby.

The benefits of Tuzulby are expected to be comparable to that of the reference medicine Ritalin; it improves the attention and behaviour of people with ADHD throughout the day. The most common side effects with Truzulby are decreased appetite, insomnia, nervousness, headache, nausea and dry mouth.

The full indication is:

> Tuzulby is indicated as part of a comprehensive treatment programme for attention-deficit / hyperactivity disorder (ADHD) in children aged 6 years of age and over when remedial measures alone prove insufficient. Treatment must be under the supervision of a specialist in childhood behavioural disorders. Diagnosis should be made according to Diagnostic and Statistical Manual of Mental Disorders Fourth Edition (DSM-IV) criteria or the guidelines in International Classification of Diseases,Tenth Revision (ICD-10) and should be based on a complete history and evaluation of the patient. Diagnosis cannot be made solely on the presence of one or more symptoms.

[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

Treatment with Tuzulby must be initiated under the supervision of a 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.