



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 January 2021
EMA/CHMP/12859/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Ontozry cenobamate

On 28 January 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ontozry, intended for adults with epilepsy whose disease is not adequately controlled despite a history of treatment with at least 2 anti-epileptic medicinal products. The applicant for this medicinal product is Arvelle Therapeutics Netherlands B.V.

Ontozry will be available as 12.5 mg tablet + 25 mg film-coated tablet (initiation pack), 50 mg, 100 mg, 150 mg and 200 mg film-coated tablet. The active substance of Ontozry is cenobamate, an antiepileptic (ATC code: N03AX). Cenobamate has a dual mechanism of action, with positive allosteric modulation of the GABA_A receptors and enhancement of sodium channel inactivation with inhibition of the persistent component of the sodium current.

The benefits with Ontozry are its ability to reduce the frequency of seizures at doses of 100 mg to 400 mg/day. The most common side effects are somnolence, dizziness, fatigue and headache.

The full indication is:

Ontozry is indicated for the adjunctive treatment of focal-onset seizures with or without secondary generalisation in adult patients with epilepsy who have not been adequately controlled despite a history of treatment with at least 2 anti-epileptic medicinal products.

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.

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

