Angelini Pharma

ONTOZRY® cenobamat

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.[1]

INCREASING REAL-WORLD EVIDENCE CONFIRMS THE BENEFITS OF INITIATING CENOBAMATE AT AN EARLIER STAGE°[2]

BLESS STUDY

KEY POINTS from the second interim analysis over 24 weeks

Multicenter, observational cohort study to study Ontozry outcomes at 24 weeks in 388 adults with uncontrolled focal epilepsy despite prior treatment with at least 2 ASMs.

Cenobamate as add-on reduced the monthly seizure frequency:[2]

Median intra-patient percentage reduction in monthly seizure frequency: **59.9%** ***(Baseline to 24 weeks; −87.3 to −19.2)***

≥50% response rate: 59% (n=229)
≥Sustained seizure freedom: 11.3% (n=44)

Early users (2-3 previous ASMs)°experienced a greater reduction in monthly seizure frequency compared to late (>3 previous ASMs)*[2]

Median intra-patient percentage reduction in monthly seizure frequency: **78.0% vs 55.5%**

≥50% response rate: 76.3% (n=58) vs 54.8 (n=171)
Sustained seizure freedom: 22.4% (n=17)
≥vs 8.7% (n=27)

The safety profile of cenobamate was predictable and manageable:[2]

- **No serious adverse events (SAEs) were reported**
- **63.5% of participants maintained the prescribed dose, and only 5.2% permanently discontinued**

Patients with at least one adverse drug reactions (ADRs): 5.3% among early users and 23.4% among late users

Adjunctive cenobamate therapy allows the reduction of concomitant ASMs:[2]

- **The proportion of participants who interrupted at least one concomitant ASM increased in both early and late users**

° Number of previous ASMs used before cenobamate initiation, median (IQR): 3.0 (2.0-3.0), 9.6% (n=76).
Cenobamate is indicated as an add-on medication for adult epilepsy patients, not adequately controlled despite of history with at least 2 anti-epileptic medicinal products[1]

* Number of previous ASMs used before cenobamate initiation, median (IQR): 7.0 (5.9-9.0), 80.4% (n=312)

ADR: adverse drug reaction; **ASM:** antiseizure medication.

1. Ontozry Summary of Product Characteristics 4.1
2. Lattanzi S, et al. BLESS Study Group. Effectiveness and safety of adjunctive cenobamate in people with focal-onset epilepsy: Interim results after 24-week observational period from the BLESS study. Epilepsia. 2025;66:2239-2252.

▼ Detta läkemedel är föremål för utökad övervakning.

Ontozry® (cenobamat) 12,5 mg odragerad tablett samt 25 mg, 50 mg, 100 mg, 150 mg och 200 mg filmdragerade tabletter. Rx F. ATC-kod: N03AX25 - antiepileptika, övriga antiepileptika. Indikation: Ontozry är indicerat som tilläggsbehandling av fokala anfall, med eller utan sekundär generalisering hos vuxna patienter med epilepsi, som inte kontrollerats tillräckligt trots tidigare *b*ehandling med minst två antiepileptika. Kontraindikationer: Överkänslighet mot den aktiva substansen eller mot något hjälpämne, ärftligt kort QT-syndrom. Varningar: Patienter ska instrueras att uppsöka läkare om tecken på självmordstankar/självmordsbeteende *u*ppstår, samt om tecken och symptom på läkemedelsreaktion med eosinofili och systemiska symtom (DRESS) inträffar. Innehåller laktos. Cenobamat kan minska exponeringen av substanser som metaboliseras via CYP3A4, CYP2B6 samt öka exponeringen av substanser som metaboliseras via CYP2C19. Cenobamat rekommenderas inte till fertila kvinnor som inte använder preventivmedel eller vid amning. MAH: Angelini Pharma S.p.A. Lokal kontakt: Angelini Pharma Nordics, nordic.medinfo@angelinipharma.com. Datum för senaste översyn av SPC: 2/2025. För pris och ytterligare information, se www.fass.se.

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