Phentermine/Topiramate: Adis Evaluation

Key Points

- A fixed-dose combination of phentermine (sympathomimetic amine) and topiramate being developed by VIVUS (a subsidiary of Icahn Enterprises) for the treatment of obesity, sleep apnoea syndrome, diabetes and NASH
- Received its pediatric first approval on 20 July 2022 in the USA
- Approved, as an adjunct to a reduced-calorie diet and increased physical activity, for chronic weight management in pediatric patients aged ≥ 12 years with BMI in the 95th percentile or greater

Summary

Phentermine/topiramate extended-release capsule (Qsymia®) is a fixed-dose combination of phentermine and topiramate, which is being developed by VIVUS (a subsidiary of Icahn Enterprises) for the treatment of obesity, sleep apnoea syndrome, type 2 diabetes mellitus and non-alcoholic steatohepatitis (NASH).

The once-daily formulation of phentermine (a sympathomimetic amine) and topiramate is designed to combat obesity by decreasing appetite and increasing satiety.

In July 2022, phentermine/topiramate received its first approval in the USA, as an adjunct to a reduced-calorie diet and increased physical activity, for chronic weight management in pediatric patients aged ≥ 12 years with BMI in the 95th percentile or greater standardized for age and sex. Phentermine/topiramate is approved in the US and South Korea for obesity in adults. Clinical development of phentermine/topiramate for sleep apnoea syndrome and type-2 diabetes in obese patients and preclinical development for NASH is ongoing in the US.

Dhillon, S. Pediatric Drugs. 2022. https://doi.org/10.1007/s40272-022-00532-z