CNS Spectrums

www.cambridge.org/cns

Abstracts

Cite this article: Wilhelm A, PhD, Anderson KE, MD, Fernandez HH, MD, Barkay H, PhD, Chaijale N, PhD, Send AF, PhD, Savola J-M, MD, PhD, Gordon MF, MD (2021). Comparison of Safety and Tolerability of Deutetrabenazine During Titration and Maintenance in Patients with Tardive Dyskinesia. *CNS Spectrums* **26**(2), 164–180.
https://doi.org/10.1017/S1092852920002643

Comparison of Safety and Tolerability of Deutetrabenazine During Titration and Maintenance in Patients with Tardive Dyskinesia

Amanda Wilhelm, PhD[1], Karen E. Anderson, MD[2], Hubert H. Fernandez, MD[3], Hadas Barkay, PhD[4], Nayla Chaijale, PhD[1], Alexander F. Send, PhD[1], Juha-Matti Savola, MD, PhD[5] and Mark Forrest Gordon, MD[1]

[1]Teva Pharmaceutical Industries Ltd., West Chester, PA, USA, [2]Georgetown University, Washington, DC, USA, [3]Cleveland Clinic, Cleveland, OH, USA, [4]Teva Pharmaceutical Industries Ltd., Netanya, Israel, and [5]Teva Pharmaceutical Industries Ltd., Basel, Switzerland

Presenting Author: Amanda Wilhelm

Abstract

Background. Deutetrabenazine is approved to treat tardive dyskinesia (TD) in adults and is titrated weekly by 6 mg/day, from 12 to 48 mg/day, based on dyskinesia control and tolerability. This analysis compared the safety of deutetrabenazine during titration versus maintenance.
Methods. Safety was assessed during titration versus maintenance using integrated data from two 12-week placebo-controlled studies (ARM-TD and AIM-TD) and the open-label extension study. Rates were compared for overall and serious adverse events (AEs), AEs leading to discontinuation, treatment-related AEs, common AEs (≥4%), and specific AEs (parkinsonism, suicidal ideation, akathisia, restlessness).
Results. In titration versus maintenance, AE rates with placebo (n=130) were: overall, 43.1% vs 25.4%; serious, 4.6% vs 2.3%; leading to discontinuation, 3.1% vs 0; treatment-related, 26.9% vs 10.0%. For placebo, common AEs during titration were somnolence, headache, nausea, fatigue, and dry mouth; none occurred during maintenance. In titration versus maintenance, AE rates in fixed-dose deutetrabenazine 12–36 mg (n=216) were: overall, 33.3–38.9% vs 22.2–29.2%; serious, 2.8–6.9% vs 0–1.4%; leading to discontinuation, 2.8–5.6% vs 0; treatment-related, 8.3–16.7% vs 8.3–13.9%. For fixed-dose deutetrabenazine, common AEs during titration were headache, diarrhea, nasopharyngitis, depression, hypertension, and dry mouth; headache was the only common AE during maintenance. In titration versus maintenance, AE rates with flexible-dose deutetrabenazine (n=168) were: overall, 49.4% vs 32.7%; serious, 3.6% vs 2.4%; leading to discontinuation, 2.4% vs 0.6%. For flexible-dose deutetrabenazine, the only common AE during titration was somnolence; none occurred during maintenance. Rates of parkinsonism, suicidal ideation, akathisia, and restlessness were low and comparable in titration and maintenance.
Conclusions. Deutetrabenazine was well-tolerated, with AE rates similar to placebo during both phases; AE rates were higher during titration and decreased during maintenance.
Funding. Teva Pharmaceutical Industries Ltd., Petach Tikva, Israel

Long-Term Efficacy and Safety of Deutetrabenazine for Chorea in Huntington's Disease: Results From the ARC-HD Open-label Study

Samuel Frank, MD[1], Claudia M. Testa, MD, PhD[2], David Stamler, MD[3], Elise Kayson, MS[4], David Oakes, PhD[4], Christina Vaughan, MD, MHS[5], Jody Goldstein, BS[6], Jacquelyn Whaley, MS[7], Mat D. Davis, PhD[8], Mark Forrest Gordon, MD[8], Juha-Matti Savola, MD, PhD[9] and on behalf of the Huntington Study Group ARC-HD Investigators

[1]Beth Israel Deaconess Medical Center and Harvard Medical School, Boston, MA, USA, [2]Virginia Commonwealth University, Richmond, VA, USA, [3]Teva Pharmaceutical Industries Ltd., La Jolla, CA, USA, [4]University of Rochester, Rochester, NY, USA, [5]University of Colorado, Aurora, CO, USA, [6]Huntington Study Group, Rochester, NY, USA, [7]Center for Health + Technology, University of Rochester, Rochester, NY, USA, [8]Teva Pharmaceutical Industries Ltd., West Chester, PA, USA, and [9]Teva Pharmaceutical Industries Ltd., Basel, Switzerland

Presenting Author: Samuel Frank

CAMBRIDGE UNIVERSITY PRESS