



XPHOZAH® (tenapanor) – Time to First Bowel Movement after XPHOZAH Administration

Key Information

US Prescribing Information¹

- XPHOZAH is indicated to reduce serum phosphorus in adults with chronic kidney disease on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy.

Phase 1 Study ([NCT02819687](#))²

- A Phase 1, randomized, double-blind, placebo-controlled, single-center study evaluated the pharmacokinetics and pharmacodynamics of multiple ascending doses of XPHOZAH (3, 10, 30, or 100 mg) in healthy volunteers (N=40) for 7 days.
 - The median time to first bowel movement was lower (faster) in the XPHOZAH group vs placebo group and lower with higher doses (30 and 100 mg) of XPHOZAH vs lower doses (3 and 10 mg).

XPHOZAH: Time to First Bowel Movement after XPHOZAH Administration

Phase 1 Study ([NCT02819687](#))²

Study Design

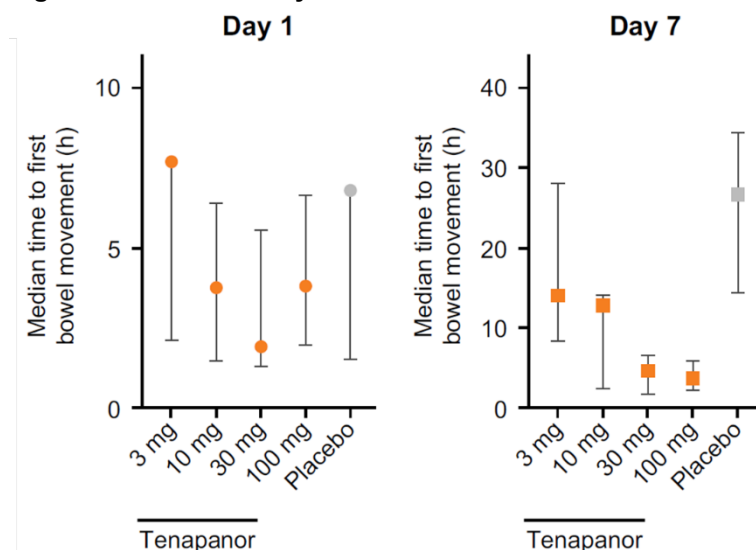
- A Phase 1, randomized, double-blind, placebo-controlled, single-center study evaluated the pharmacokinetics and pharmacodynamics of multiple ascending doses of XPHOZAH in healthy volunteers (N=40).
- The participants were randomized 4:1 to receive XPHOZAH 3, 10, 30, or 100 mg or placebo once daily for 7 days.
- The time from the first morning dose of the drug to the first bowel movement experienced by the participant was considered the median time to the first bowel movement.

Results

- The age of the healthy participants ranged from 19-65 years and their body mass index (BMI) ranged from 18-29.9 kg/m².
- The time to first bowel movement was faster in the XPHOZAH group vs placebo group. A post hoc analysis showed a significantly shorter median time to the first bowel movement across all XPHOZAH dose groups compared with the placebo group (overall treatment difference, $p<0.05$).
- Participants who received higher doses of XPHOZAH (30 and 100 mg) had a lower median time to the first bowel movement compared with those who received lower doses (3 and 10 mg), see **Figure 1**.



Figure 1. Phase 1 Study: Median Time to First Bowel Movement in Healthy Participants²



Data are presented as medians. Error bars represent the 25th and 75th percentiles.

References

1. XPHOZAH® (tenapanor) Tablets [package insert]. Waltham, MA: Ardelyx, Inc. [\[Link\]](#)
2. King AJ, Chang L, Li Q, et al. NHE3 inhibitor tenapanor maintains intestinal barrier function, decreases visceral hypersensitivity, and attenuates TRPV1 signaling in colonic sensory neurons. *Am J Physiol Gastrointest Liver Physiol*. 2024;326(5):G543-G554. [\[PubMed\]](#)