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Clinical Pharmacology and Real-World Performance of Hezkue®

A Novel Sildenafil Oral Suspension Without the Negative Food Effect Seen in Conventional Formulations

Steven Kaplan, MD[1], Sabine Brookman-May, MD[2], Geoffrey Barnes, MD[3], Kerri Clarkson, RN[4], Noah Guralnik, MS[4]

1: Men's Wellness Program, Mount Sinai Health System and Icahn School of Medicine at Mount Sinai, 2: Ludwig Maximilian University of Munich, Dept. of Urology, 3: Division of Cardiovascular Medicine Department of Internal Medicine University of Michigan, 4: Synergy Research Inc.

Introduction

Conventional sildenafil tablets are effective in treating erectile dysfunction (ED) but suffer from pharmacokinetic drawbacks that can diminish real-world efficacy. Chief among these is a pronounced negative food effect. Fat-containing meals delay absorption and lower peak plasma concentrations (Cmax), often resulting in delayed onset of action and reduced spontaneity. Hezkue®, a metered-dose oral suspension of sildenafil developed by Aspargo Labs, was designed to address these limitations.

Methods

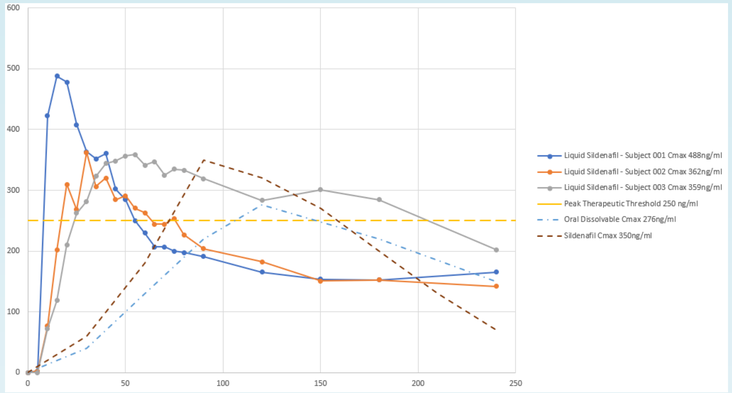
Data were derived from three Phase 1 clinical pharmacology studies evaluating Hezkue under both fed and fasted conditions. These studies include direct comparisons to conventional film-coated sildenafil tablets (Viagra®) and have assessed pharmacokinetic parameters such as Cmax, Tmax, and AUC across dense sampling intervals to characterize absorption kinetics and food-effect variability. Results were then contextualized using real-world observational data on patient experience, satisfaction, and adherence. Additionally, published pharmacological and bioequivalence data on other marketed sildenafil products were reviewed to benchmark the performance of Hezkue against existing ED therapies.

Results

Across both clinical and observational datasets, Hezkue demonstrated rapid and consistent absorption. Therapeutic plasma levels (250 ng/mL) were typically reached within 10–20 minutes. Individual subject Cmax values exceeded 800 ng/mL in some cases. Unlike conventional tablets, the suspension maintained favorable pharmacokinetics even in the fed state. In the food-effect crossover study, Cmax in the fed state was 488 ng/mL for Hezkue, compared to approximately 350ng/mL for standard sildenafil tablets under similar conditions. Importantly, while food significantly delayed Tmax and reduced Cmax for tablet formulations, Hezkue showed stable absorption across fed and fasted conditions, mitigating the traditional food effect associated with PDE5 inhibitors. Real-world findings further supported these advantages. In multiple independent studies, men transitioning from tablets to Hezkue reported significantly higher satisfaction, improved adherence, and greater spontaneity. Patients cited reduced pressure to time drug intake relative to meals or sexual activity, with the suspension's ease of use and rapid effect supporting more natural integration into their routines.

Comparative PK Results –

HEZKUE vs other Sildenafil Formulations (Fed State)



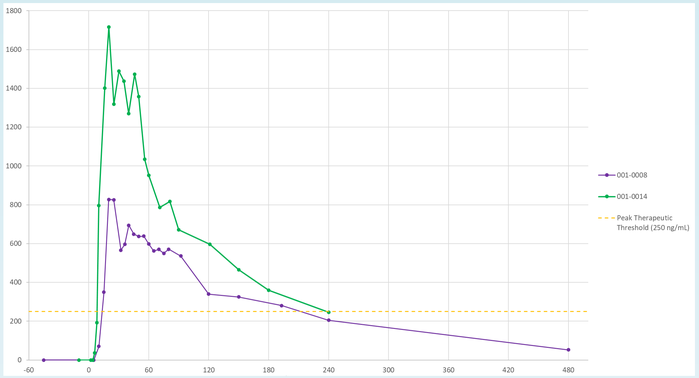
To contextualize HEZKUE's absorption profile, the above graph compares peak plasma concentrations (Cmax) from individual subjects administered HEZKUE under fed conditions to benchmark data from both Viagra® and orodispersible/chewable sildenafil formulations.

HEZKUE subjects achieved Cmax values exceeding the therapeutic threshold of 250 ng/mL, with Subject 001 reaching 488 ng/mL —substantially higher than the orodispersible and chewable products (276 ng/mL) and even surpassing the reference value for Viagra® (350 ng/mL).

This data highlights the unique potential of HEZKUE to deliver fast and robust absorption under real-world, post-meal conditions—differentiating it from other delivery modalities traditionally limited by food effect.

Preliminary PK Results –

HEZKUE Turbo (Fasted State)



This plot presents an early data snapshot from an ongoing pharmacokinetic study evaluating HEZKUE Turbo, the next-generation formulation of Aspargo's liquid sildenafil. Shown here are the fasted-state profiles of Subjects 008 and 014, who exhibited exceptionally rapid and high systemic absorption. Plasma sildenafil levels peaked at 827 ng/mL for Subject 008 and 1716 ng/mL for Subject 014, both within 20 minutes post-dose—surpassing the therapeutic threshold (250 ng/mL) more than threefold in under half an hour.

While the study is still in progress, these individual profiles demonstrates the remarkable absorption potential of the HEZKUE Turbo formulation.

These early findings support the program's goal of developing the fastest-acting, most food-effect-resistant sildenafil option available for the treatment of ED.

Conclusion

Hezkue overcomes critical limitations of existing sildenafil therapies by providing a reliable, rapid-onset, alternative that is not impaired by food intake. Its favorable pharmacokinetic profile—rapid absorption, high peak concentrations, and food-effect neutrality—combined with real-world evidence of enhanced patient satisfaction, position this formulation as a clinically and behaviorally meaningful innovation in ED management.

These findings support the continued clinical deployment and future investigation of Hezkue as a first-line PDE5 inhibitor therapy.

The pharmacokinetic profile of Hezkue may offer particular advantages for patients on GLP-1 receptor agonists—who often experience delayed gastric emptying—suggesting potential utility in populations affected by impaired gastric motility, though this has not yet been directly studied.

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