VAZALORE™ 325 mg Clinical Data

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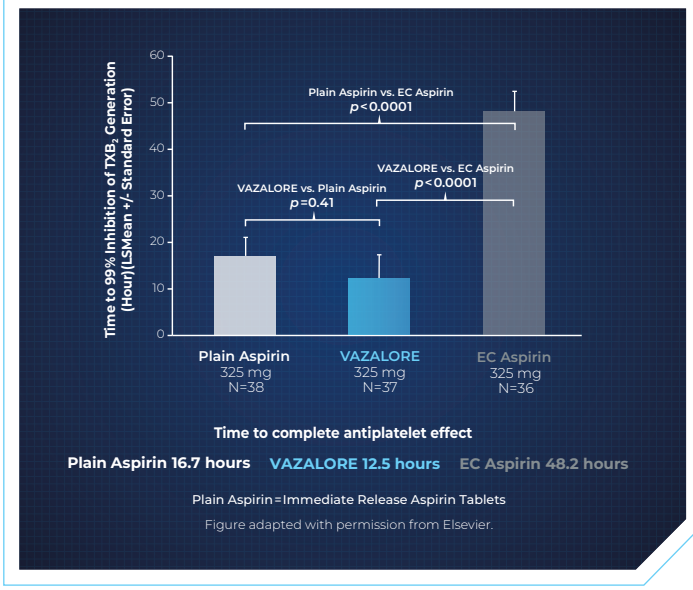
New! ASPIRIN THERAPY VAZALORE™

The information contained in this document is intended for healthcare professionals only.

Clinical Study—PK/PD Comparison: Plain Aspirin, VAZALORE, Enteric Coated Aspirin[1]

In a single-center, randomized, active-controlled, single-blind, triple crossover pharmacokinetic (PK) and pharmacodynamic (PD) study of antiplatelet activity over 3 days, in obese patients with type 2 diabetes.[1]

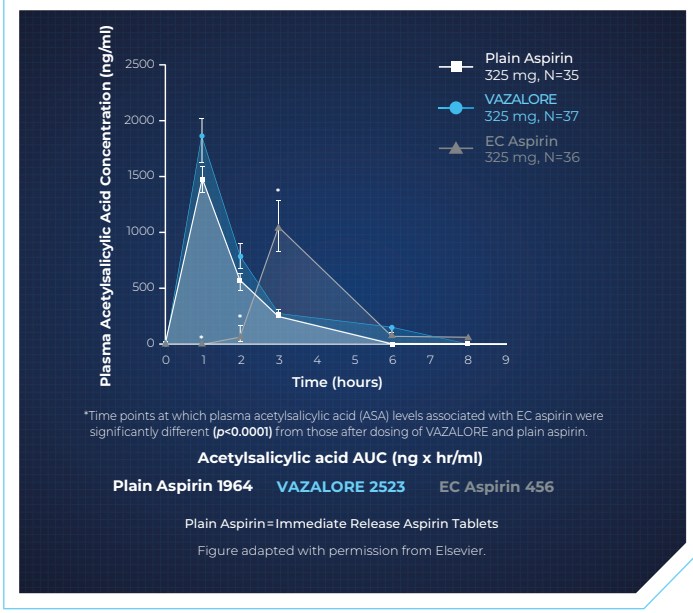
Time to Complete Antiplatelet Effect



In this study, VAZALORE achieved 99% inhibition of thromboxane B_2 generation significantly faster (12.5 hours) than enteric coated aspirin (48.2 hours) (p<0.0001)[1]

This study design cannot provide data on cardiovascular outcomes.

Plasma ASA Concentration Versus Time



In this study population the AUC of plasma concentrations were: VAZALORE (2523 ng x hr/ml), immediate release aspirin (1964 ng x hr/ml), and enteric coated aspirin (456 ng x hr/ml)

Thus, absorption with VAZALORE was 5X as high as that of enteric coated aspirin (p<0.0001)[1]

This study design cannot provide data on cardiovascular outcomes.

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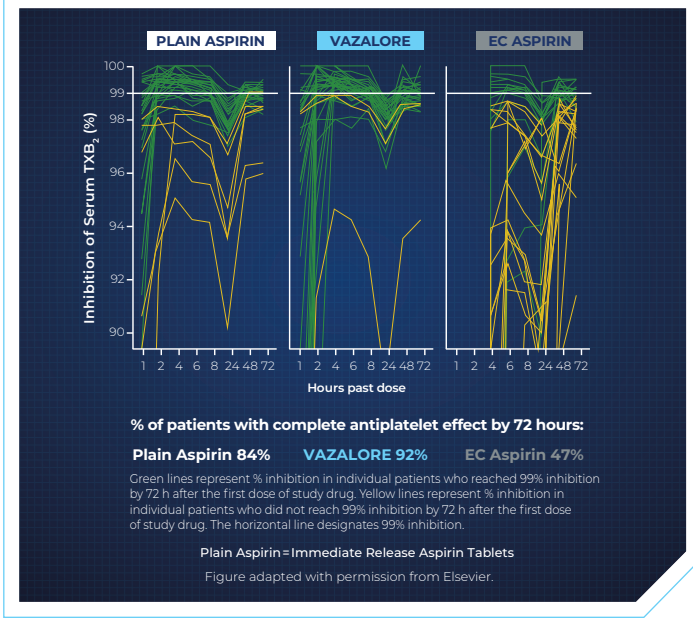
Inhibition of TXB_2 Generation by 72 Hours



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In this study population, by 72 hours, VAZALORE provided complete antiplatelet effect (≥99% inhibition of TXB_2 generation) for almost twice as many patients as enteric coated aspirin[1]

This study design cannot provide data on cardiovascular outcomes.

Clinical Study—Upper GI Injury: Plain Aspirin vs VAZALORE[2]

In a randomized, single-blind, multicenter active-controlled study of upper GI damage of aspirin in healthy subjects following 7 days of oral 325 mg once daily, immediate release aspirin tablets or VAZALORE.[2]

Upper GI Damage Comparison

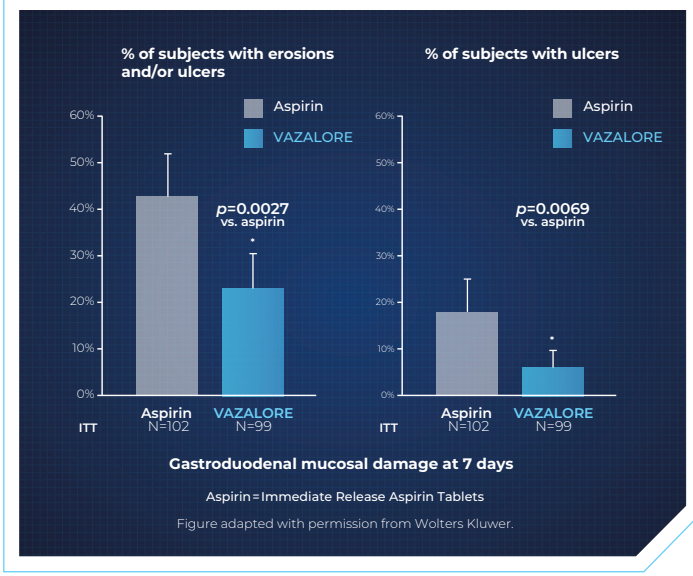

Figure adapted with permission from Wolters Kluwer.

In this study, VAZALORE caused significantly fewer erosions and ulcers than immediate release aspirin after 7 days of therapy[2]:

- 47% lower risk of erosions or ulcers (NNT=5)
- 71% lower risk of ulcers (NNT=8)

References: 1. Bhatt DL, Grosser T, Dong JF, et al. Enteric coating and aspirin nonresponsiveness in patients with type 2 diabetes mellitus. *J Am Coll Cardiol*. 2017;69(6):603-612. **2.** Cryer B, Bhatt DL, Lanza FL, et al. Low-dose aspirin-induced ulceration is attenuated by aspirin–phosphatidylcholine: a randomized clinical trial. *Am J Gastroenterol*. 2011;106(2):272-277.

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