

## To whomsoever it may concern

### **Subject: Bioequivalence between Mesalazine 1200mg Gastro-Resistant Prolonged-Release Tablets (Zyduco® XL) and Mezavant® XL.**

Zyduco® XL is indicated for the induction and maintenance of clinical and endoscopic remission in patients with mild to moderate, active ulcerative colitis.<sup>1</sup>

We confirm that Zyduco® XL (PLGB 58839/0018) has been proven to be bioequivalent to Mezavant® XL (PL 16189/0142) from Takeda UK Ltd and Lialda® 1.2g delayed-release tablets NDA# 022000 from Takeda Pharms USA which have similar qualitative composition and belongs to same Global Marketing Authorization.<sup>2</sup>

Mesalazine plasma concentrations produced by the administration of a single dose of the studied formulations were processed to establish their pharmacokinetic profile. The direct measurements of this study were the plasma concentrations of mesalazine.<sup>2</sup>

Because of the high variability, if the percent intra- subject CV was greater than or equal to 30%, reference scaled average bioequivalence was to be used to determine if the test and reference products were bioequivalent. If the percent intra- subject CV was less than 30%, conventional methods of average bioequivalence were to be used to assess bioequivalence criteria.<sup>2</sup>

The results showed that the upper bound of the 95% confidence interval of the linearized criteria,  $\eta$ , was below zero, and that the point estimate of the Test to Reference geometric mean ratio fell within the bioequivalence range of 80.00-125.00% for C<sub>max</sub> (91.30%), AUC<sub>0-t</sub> (91.06%) and AUC<sub>8-48</sub> (91.19%) parameters respectively.<sup>2</sup>

**Therefore, Mesalazine 1200mg Gastro-Resistant Prolonged-Release Tablets (Zyduco® XL) is judged to be bioequivalent to Mezavant® XL.**

**Signed by:**

**Gaurav Soni**

Head of Regulatory Affairs

References: 1. Zyduco® XL. Summary of Product Characteristics. <https://www.medicines.org.uk/emc/product/100638/smpc> [Accessed March 2025] 2. Data on File. Zydus Pharmaceuticals UK Ltd. [Bioequivalence data]

Mezavant® XL is a registered trademark of Takeda UK Ltd.  
Lialda® is a registered trademark of Shire LLC.  
Zyduco® XL is a registered trademark of Zydus Pharmaceuticals UK Ltd.



Please scan the QR code to access the full prescribing information of Zyduco® XL

**Legal Category:** POM

**Price:** 60 tablets Blister Pack £31.35 | 120 tablets Bottle Pack £60.95

**Marketing Authorization Number:** PLGB 58839/0018

**Marketing Authorization Holder:** Zydus Pharmaceuticals UK Ltd., Sandretto Building, Cavalry Hill Industrial Park, Weedon, Northampton, England NN74PP, UK

**Date of Preparation:** Mar 2025 **Code:** ZUK/ZXL/BDS/25/03/01

Please refer to full SmPC text before prescribing. Adverse events should be reported. Reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in Google Play or App Store. Adverse events should also be reported to Zydus Pharmaceuticals UK Ltd.'s Pharmacovigilance Dept. on Tel: 0800 9956034 or Email: [DrugSafety@ZydusUK.com](mailto:DrugSafety@ZydusUK.com)