

# Zyduco<sup>®</sup> XL Review:

Mesalazine 1200 mg

Gastro-Resistant Prolonged-Release Tablets

A Cost-Effective, Bioequivalent Alternative to Mezavant<sup>®</sup> XL for Inflammatory Bowel Disease (IBD) treatment<sup>1-7</sup>

## Overview

Zyduco<sup>®</sup> XL (Mesalazine 1200mg) offers Integrated Care Boards (ICBs) a significant opportunity to reduce drug expenditure without compromising on effectiveness or efficacy to you or your patient<sup>1-7</sup>.

- **Proven Bioequivalence:**  
Licensed and demonstrably bioequivalent to the market leader, Mezavant<sup>®</sup> XL<sup>6</sup>.
- **Immediate Cost Savings:**  
Delivers a **27% saving** on the standard 60-tablet pack versus Mezavant<sup>®</sup> XL, rising to **29%** on the larger 120-tablet pack, optimising your budget and reducing carbon footprint through less frequent dispensing<sup>2,3</sup>.
- **Substantial System-Wide Savings:**  
Based on an average ICB, a **100% conversion could save approximately £70,000 per annum**<sup>4,5</sup>.
- **Globally Established:**  
Available since 2016 in the US, where it now holds a **36% market share** (fulfilling over 425,000 scripts annually)<sup>8</sup>.
- **Dedicated Transition Support:**  
Zyduis UK provides full support to ensure a smooth, managed switch, including stock management and communication resources.

## Background & Place in Therapy

The use of Mesalazine (an aminosalicylate) has been a mainstay treatment for Inflammatory Bowel Disease (IBD), the term used for ulcerative colitis and Crohn's disease, for many years due to its anti-inflammatory and mucosal healing properties<sup>9</sup>.

In the UK, Ulcerative Colitis affects over 1 in 400 people, representing a significant long-term cost to the NHS in both primary and secondary care. Mesalazine forms the foundation of treatment for the majority of these patients, allowing for the control of both flare-ups and ongoing maintenance to prevent returning symptoms.

Mesalazine is available in many forms, such as tablets and suppositories, and in various strengths. More recently, these can be gastro-resistant or modified-release tablets like Zyduco<sup>®</sup> XL, designed to deliver the drug to the site of inflammation.

Prescribing Information and Adverse Event Reporting can be found on Page 6 of this document

# Zyduco<sup>®</sup> XL

Mesalazine 1200 mg  
Gastro-Resistant Prolonged-Release Tablets

## Overview of Main Product Features

Zyduco<sup>®</sup> 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>

Each tablet contains 1200 mg Mesalazine and <1mmol sodium (23 mg) per 4 tablets, essentially 'sodium-free'. It is intended for **once daily** use and oral administration. The tablets must not be crushed or chewed and should be taken with food.

Indication <sup>1</sup>	Dosage <sup>1</sup>	Notes <sup>1</sup>
Induction of remission	2.4g - 4.8g (2-4 tablets) once daily	Evaluate effect at 8 weeks if using 4.8g dose.
Maintenance of remission	2.4g (2 tablets) once daily	

For use in Children and Adolescents, please refer to the full Summary of Product Characteristics.

**Zyduco<sup>®</sup> XL** comes in two pack sizes: a 60-tablet Blister Pack and a 120-tablet Bottle Pack. It should be stored below 25°C, in its original packaging to protect from moisture, and has a 24-month shelf life<sup>1</sup>.



Not to size for illustration purposes only

## Tolerability & Safety

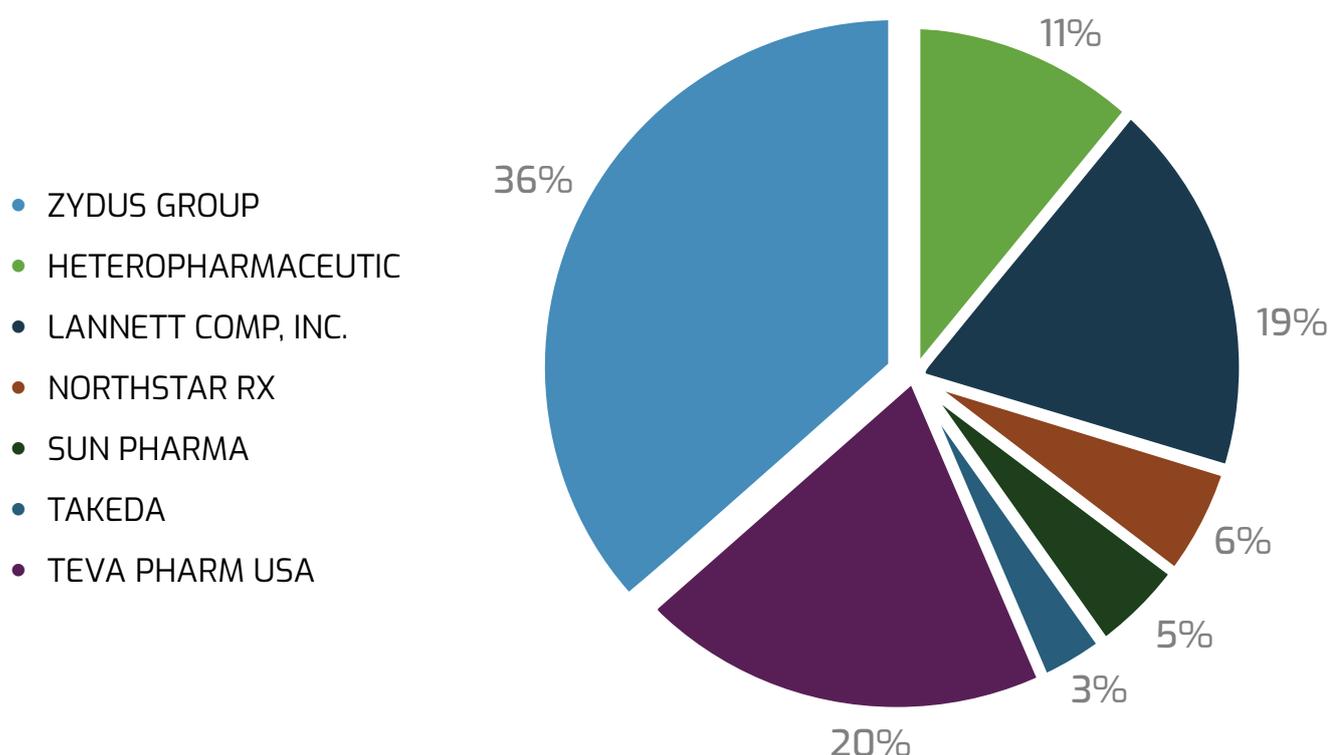
Mesalazine was first approved in the US in 1987 and has a long-standing, well-documented safety profile. In 2023 it was the 202nd most prescribed medication in the United States, with more than 2 million prescriptions per annum<sup>10</sup>.

Zyduco<sup>®</sup> XL benefits from this established profile alongside its own significant real-world experience. **It has been available as a generic in the US since 2016**, where it is now the market leader within its strength and form, holding a 36% market share with 425K prescriptions written in a recent 12-month period<sup>9</sup>. This extensive use provides strong reassurance regarding its tolerability and safety in a large patient population.

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**Chart showing top 7 companies by Market Share of Mesalazine**  
(July 2024-June 2025 by Rx Total 1,16m)



For further information on its tolerability and safety profile please refer to the Summary of Product Characteristics

## Bioequivalence

Zyduco<sup>®</sup> XL was assessed against Mezavant<sup>®</sup> XL from Takeda UK Ltd. 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>6</sup>.

Therefore, Mesalazine 1200mg Gastro-Resistant Prolonged-Release Tablets (Zyduco<sup>®</sup> XL) is judged to be bioequivalent to Mezavant<sup>®</sup> XL<sup>1,6,7</sup>.

# Zyduco<sup>®</sup> XL

Mesalazine 1200 mg

Gastro-Resistant Prolonged-Release Tablets

## Costs and Savings\*

Switching to Zyduco<sup>®</sup> XL generates immediate and recurring savings for the NHS, directly releasing funds for reinvestment into other patient services.

Zyduco<sup>®</sup> XL comes in two pack sizes: a 60-tablet Blister Pack (£31.35) and a 120-tablet Bottle Pack (£60.95)<sup>1,2</sup>. In the UK, the current market leader is Mezavant<sup>®</sup> XL 1200mg<sup>5</sup>

Comparing the pricing demonstrates clear savings<sup>1,2,3,5,7</sup>:

Price per 60 tablets		Potential Cost Saving using Zyduco <sup>®</sup> XL	Price per 120 tablets		Potential Cost Saving using Zyduco <sup>®</sup> XL 1200mg
Mezavant <sup>®</sup> XL 1200mg	Zyduco <sup>®</sup> XL 1200mg		Mezavant <sup>®</sup> XL 1200mg	Zyduco <sup>®</sup> XL 1200mg	
£42.95	£31.35	£11.60	£85.90	£60.95	£24.95
		27%			29%

## Savings for ICBs/CCGs

Zyduco<sup>®</sup> XL can offer significant, predictable savings to ICBs and CCGs.

Based on an average ICB<sup>4,5</sup> that dispenses 4,000 Mesalazine prescriptions per annum (equating to approximately 6,700 packs of 60 tablets):

- A **50% conversion** to Zyduco<sup>®</sup> XL would generate savings of **£35,000 per annum**.
- A **100% conversion** would generate savings of **£70,000 per annum**.

# Zyduco<sup>®</sup> XL

Mesalazine 1200 mg

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## Resources and Transition Support

Zydus UK appreciates that transitioning from one product to another requires careful management. We are committed to ensuring a smooth and straightforward process by:

- Working directly with you to monitor stock levels within local wholesalers.
- Providing template stock switch letters and communication materials for healthcare professionals and patients.
- Offering dedicated support to address any queries during the transition period.

## In Summary Zyduco<sup>®</sup> XL

- **Proven Bioequivalence:**

Licensed and demonstrably bioequivalent to the market leader, Mezavant<sup>®</sup> XL<sup>6</sup>.

- **Immediate Cost Savings:**

Delivers a **27% saving** on the standard 60-tablet pack versus Mezavant<sup>®</sup> XL, rising to **29%** on the larger 120-tablet pack, optimising budget and reducing carbon footprint through less frequent dispensing<sup>2,3</sup>.

- **Substantial System-Wide Savings:**

Based on an average ICB, a **100% conversion could save approximately £70,000 per annum**<sup>4,5</sup>.

- Globally Established: Available since 2016 in the US, where it now holds a **36% market share** (fulfilling over 425,000 scripts annually)<sup>8</sup>.
- Dedicated Transition Support: Zydus UK provides full support to ensure a smooth, managed switch, including stock management and communication resources.

## Next Steps for Formulary Consideration

For a detailed savings forecast tailored to your ICB, or to discuss a supported transition plan, please contact our team.

For more information, please email us at [office@zydusuk.com](mailto:office@zydusuk.com) or call us on 01604 504166

# Zyduco<sup>®</sup> XL

Mesalazine 1200 mg

Gastro-Resistant Prolonged-Release Tablets

## Abbreviated Prescribing Information

**Prescribing Information:** Zyduco<sup>®</sup> XL 1200 mg Gastro-Resistant Prolonged-Release Tablet. **Composition:** Each tablet contains 1200 mg mesalazine and <1mmol sodium (23 mg) per 4 tablets, essentially 'sodium-free'. **Always refer to the full Summary of Product Characteristics (SmPC) before prescribing.** **Indication:** Adults, including the elderly (>65 Years) - For induction and maintenance of clinical and endoscopic remission in patients with mild to moderate, active ulcerative colitis. Children and adolescents (weighing >50 kg and age ≥10 years) - For the induction and maintenance of clinical and endoscopic remission in patients with mild to moderate, active ulcerative colitis. **Dosage & Administration:** Zyduco<sup>®</sup> XL is intended for once daily, oral administration. The tablets must not be crushed or chewed and should be taken with food. Adults, including the elderly (>65 years) - For induction of remission: 2.4 g to 4.8 g (2-4 tablets) should be taken once daily. The highest dose of 4.8g/day is recommended for patients not responding to lower doses of mesalazine. When using the highest dose (4.8 g/day), the effect of the treatment should be evaluated at 8 weeks. For maintenance of remission: 2.4 g (2 tablets) should be taken once daily. Children and adolescents (weighing >50 kg and age ≥10 years) - For induction of remission (initial 8 weeks): 2.4 g to 4.8 g (2-4 tablets) should be taken once daily. For maintenance of remission: 2.4 g (two tablets) should be taken once daily. Mesalazine 1200mg tablets should not be used by paediatric patients weighing ≤50 kg and should not be used in paediatric patients <10 years of age. **Contraindications:** History of hypersensitivity to salicylates (including mesalazine) or any excipients of Zyduco<sup>®</sup> XL. Severe renal impairment (GFR <30 mL/min/1.73m<sup>2</sup>) and/or severe hepatic impairment. **Precautions and Warnings:** Use cautiously in patients with mild to moderate renal impairment - renal function evaluations recommended before and during treatment. Patients with chronic lung impairment, especially asthma, should be monitored closely due to risk of hypersensitivity. Rarely, serious blood dyscrasias have been reported. If unexplained bleeding, bruising, or other symptoms occur, perform haematological investigations and terminate treatment if blood dyscrasia is suspected. Severe cutaneous adverse reactions (SCARs) like DRESS, SJS, and TEN have been reported - discontinue at the first sign of severe skin reactions. Nephrolithiasis has been reported with the use of mesalazine, including stones with a 100% mesalazine content. Ensure adequate fluid intake during treatment. **Interactions:** Use caution when combining mesalazine with nephrotoxic agents (e.g., NSAIDs, azathioprine) due to increased risk of renal adverse reactions. Concurrent use with azathioprine, 6-mercaptopurine, or other myelotoxic substances can increase the risk of blood dyscrasias and bone marrow failure. Combining mesalazine with coumarin-type anticoagulants (e.g., warfarin) may decrease anticoagulant activity. Monitor prothrombin time closely if this combination is necessary. **Pregnancy and lactation:** Should be used during pregnancy only when the benefits outweigh risks. Exercise caution when using high doses of mesalazine. Exercise caution if using mesalazine while breast-feeding and only if the benefit outweighs the risks. Sporadically, acute diarrhoea is reported in breast fed infants. **Effects on ability to drive and use machinery:** Zyduco<sup>®</sup> XL is considered to have negligible influence on these abilities. **Adverse Events:** Abdominal pain, headache, diarrhoea and nausea are the most frequently reported adverse events. Pancreatitis, pericarditis, skin rash that may be severe (eg, toxic epidermal necrolysis), and pneumonitis have been reported. **Overdose:** In case of overdose, correct hypoglycaemia, fluid and electrolyte imbalance by administration of appropriate therapy. Maintain adequate renal function. **Please refer to SmPC for full information on adverse events and management of overdose.**

**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

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Code: ZUK/ZXL/API/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)

[www.zydusuk.com](http://www.zydusuk.com)

# Zyduco<sup>®</sup> XL

Mesalazine 1200 mg

Gastro-Resistant Prolonged-Release Tablets

## References

1. Zyduco<sup>®</sup> XL 1200mg. Summary of Product Characteristics. <https://www.medicines.org.uk/emc/product/100638/smpc> accessed August 2025
2. <https://dmd-browser.nhsbsa.nhs.uk/> Accessed March 2025
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8. Data on File. Zydus Pharmaceuticals UK Ltd. [Rx data US]
9. <https://www.nhs.uk/medicines/mesalazine/about-mesalazine/> accessed August 2025
10. <https://clincalc.com/DrugStats/Top300Drugs.aspx> accessed August 2025

\*Data correct as per prices listed online for 1200 mg preparation(s), accessed Mar 2025. For cost comparison purposes, "cost per 60/120 units" was calculated by dividing the published cost per number of tablets to gain individual tablet cost, then multiplying by 60/120. For Mezavant<sup>®</sup> XL £42.95 per 60 tablets is equivalent to £0.72 per tablet.\*

Mezavant<sup>®</sup> XL is a registered trademark of Takeda UK Ltd. Zyduco<sup>®</sup> XL is a registered trademark of Zydus Pharmaceuticals UK Ltd.

**Date of Preparation:** September 2025 **Code:** ZUK/ZXL/VPD/25/09/01