

Elafibranor PK Fact Sheet

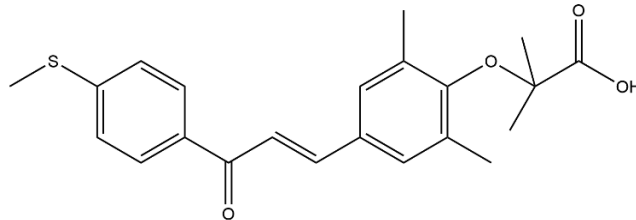
Prepared March 2026

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Details

Generic Name	Elafibranor
Trade Name	Iqirvo®
Class	PBC agents
Molecular Weight	384.49
Structure	



Summary of Key Pharmacokinetic Parameters

Linearity/non-linearity	Elafibranor and GFT1007 AUC increased between 2.9 - 3.3 -fold and 2.2 - 2.6-fold, respectively, over 2.5-fold dose increases (40 to 100 mg and 120 to 300 mg). In children, elafibranor C _{max} increased 1.9-fold and AUC 1.3-fold when the dose was increased 1.5-fold from 80 mg to 120 mg, suggesting linearity. ¹
Steady state	During once daily dosing, steady state for elafibranor was reached by 14 days, and steady state for the metabolite, GFT1007, was reached by 7 days.
Plasma half-life	Following 80 mg dose, 70.2 h.
C_{max}	Elafibranor: 802 (442) ng/mL (SD). GFT1007: 2058 (459) ng/mL (SD).
C₂₄	Not reported
AUC	Elafibranor: 3,758 (1,749) ng-h/mL (SD). GFT1007: 11,985 (7,149) ng-h/mL (SD).
Bioavailability	Not reported.
Absorption	Coadministration with a high-fat, high-calorie meal delayed elafibranor T _{max} by 30 min and GFT1007 T _{max} for 1 hour. Under fed conditions, elafibranor C _{max} and AUC decreased by 50% and 15%, respectively, compared to fasted conditions. GFT1007 C _{max} decreased by 30%. This is not deemed clinically significant and elafibranor may be administered without regard to food.
Protein Binding	~99.7%
Volume of Distribution	4,731 L
Renal Clearance	~19.3% dose recovered in urine.
Renal Impairment	No dose modification required for mild, moderate, or severe renal impairment.
Hepatic Impairment	No dose modification required for mild (Child-Pugh class A) hepatic impairment. Safety and efficacy have not been established in patients with decompensated cirrhosis. Monitor patients with cirrhosis for decompensation. Consider discontinuing elafibranor in patients who develop moderate or severe (Child-Pugh class B or C) hepatic impairment. Note: The SmPC allows for administration in Child-Pugh class B hepatic impairment without dose adjustment, this fact sheet reflects the more cautious option.

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Metabolism and Distribution

<i>Metabolized by</i>	Elafibranor: PTGR1, CYP2J2, UGT1A3, UGT1A4, UGT2B7 GFT1007: CYP2C8, UGT1A3, UGT2B7.
<i>Inducer of</i>	CYP3A4 (weak).
<i>Inhibitor of</i>	Elafibranor: BCRP, <i>BSEP</i> ² , <i>OATP1B3</i> ² . GFT1007: UGT1A6. GFT3351: <i>MRP2</i> ² , MRP3. Elafibranor, GFT1007, and GFT3351 did not inhibit P-gp, OATP1B1 OCT1, OCT2, OAT1, MATE1, MATE2-K, or OAT3. GFT1007 and GFT3351 also did not inhibit BSEP or BCRP.
<i>Transported by</i>	Elafibranor: MRP2, BCRP

Italics denotes effect seen in vitro only

References

Unless otherwise stated (see below), information is from:

Iqirvo Prescribing Information, Ipsen Biopharmaceuticals Inc, June 2024.

Iqirvo Summary of Product Characteristics, Ipsen Ltd, October 2024.

1. An Open Label, Randomized, Multicenter Study of Elafibranor in Children with Nonalcoholic Steatohepatitis. NP Goyal, A Mencin, KP Newton *et al.*, J Pediatr Gastroenterol Nutr., 2023, 77(2):160-165.
2. Personal communication, Ipsen Medical Information UK & Ireland, 14/3/25.