This guide is intended to support HCPs when prescribing IQIRVO▼ (elafibranor) and does not include all safety information. Please refer to the SmPC before prescribing IQIRVO.

This is a promotional material intended for healthcare professionals only.
This leaflet has been produced and paid for by Ipsen.



A guide to treatment with IQIRVO▼ (elafibranor)

For healthcare professionals caring for people prescribed IQIRVO

Please click here or scan the QR code to view the IQIRVO adverse event reporting and prescribing information. This medicinal product has a conditional marketing authorisation.

IPSEN IN PBC

IQIRVO (elafibranor) Patient Support

IQIRVO is indicated for the treatment of adult patients with primary biliary cholangitis (PBC):

- in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA[1]
- as a monotherapy in adults unable to tolerate UDCA[1]

This resource contains important information about IQIRVO, including its mechanism of action, clinical data, and key non-exhaustive prescribing information.

IQIVRO is licensed as second line treatment for PBC[1,2]

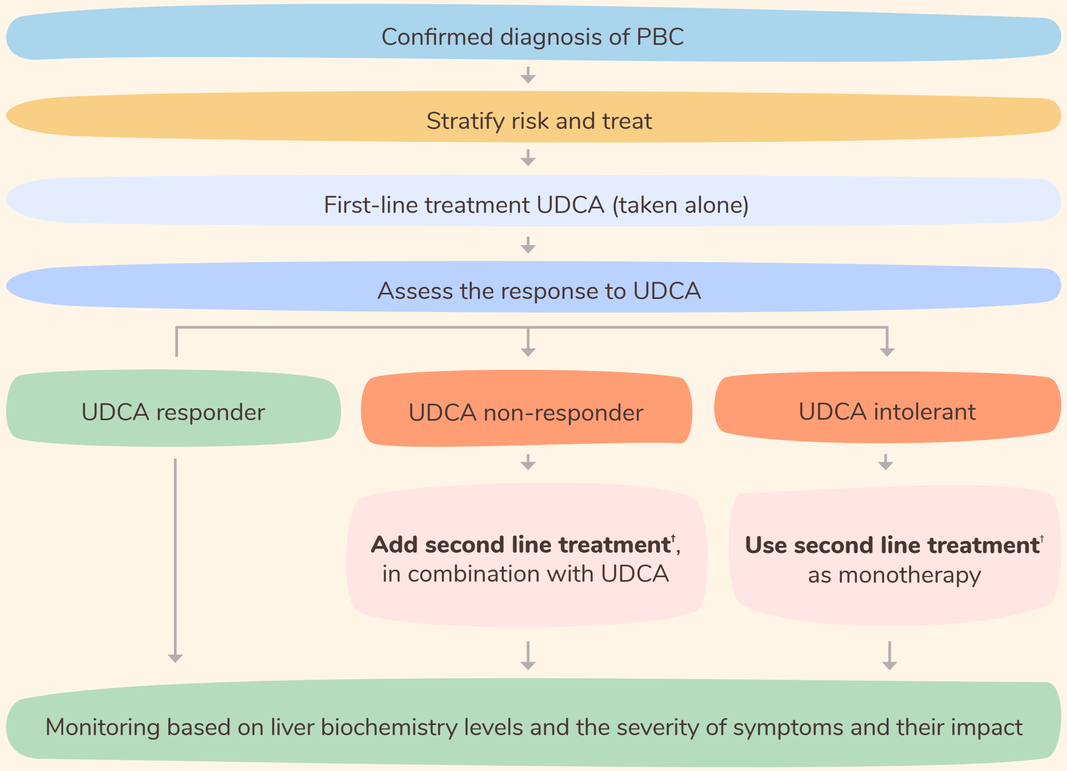


Figure aligned with the prior EASL Clinical Practice Guidelines, other second line treatments may have been received before the use of IQIRVO[1,2]

†Patients may have received other second-line treatments before IQIRVO.
‡Cholestasis response is defined in the ELATIVE trial as ALP level <1.67 x ULN, ALP level decrease ≥15% from baseline and total bilirubin ≤ULN at 52 weeks[1,3]



For further information and full prescribing information, please refer to the IQIRVO Summary of Product Characteristics (SmPC).[1]

What is IQIRVO and how does it work?

IQIRVO is an oral agonist of peroxisome proliferator-activated receptor (PPAR) exerting effect on both PPARα and PPARδ[1]

PPARs are nuclear receptors, and each subtype has distinct physiological distribution and target genes.[3,4] Activation of PPARα and PPARδ has been shown to **suppress inflammation** and **bile acid synthesis**, while **increasing bile acid detox** and **output**.[1]

In people with PBC, treatment with IQIRVO + UDCA **offers a greater cholestasis response** and ALP normalisation vs UDCA + placebo.[1‡] In the trial, 5% of patients received elafibranor alone due to UDCA intolerance.[1]

Indication

IQIRVO is indicated for the treatment of adult patients with PBC

- in combination with UDCA for adults with an inadequate response to UDCA[1]
- as monotherapy for adults with an intolerance to UDCA[1]

Contraindications

People with hypersensitivity to the active substance or any of the excipients should not take IQIRVO.[1]

Dosing

IQIRVO is a once-daily tablet for all eligible patients and does not require dose adjustments. The recommended dose of IQIRVO is 80 mg (one tablet per day).[1] It can be taken orally, with or without food.[1] The tablet should not be crushed, chewed or split prior to administration.[1]

If a patient misses their daily dose, they should not take a double dose. Instead, they should make sure to take their subsequent dose at the next scheduled time point.[1]

Use in patients with severe hepatic impairment (Child-Pugh C) is not recommended.[1]



Warnings and precautions*

Liver-related events:
If increases in liver biochemical tests and/or liver dysfunction are observed, consider interruption of IQIRVO in patients with predisposing factors. CPK should be evaluated prior and during IQIRVO treatment, patients should be advised to report promptly any unexplained muscle symptoms and treatment should be interrupted if increases in CPK or unexplained signs and symptoms of muscle injury are observed[1]

Fibrates:
Concomitant administration is not recommended[1]

Hypersensitivity:
If severe hypersensitivity reactions occur, permanently discontinue IQIRVO[1]

Fractures:
Consider the risk of fracture and monitor bone health[1]

Pregnancy and lactation:
Studies in pregnant animals have shown reproductive toxicity. IQIRVO is not recommended during pregnancy. Women of childbearing potential should continue to use effective contraception during and up to at least for 3 weeks following the final dose of IQIRVO. IQIRVO should not be used during breastfeeding and for at least 3 weeks following last dose[1]

Elevated blood creatine phosphokinase and muscle injury:
Caution should be used in patients with predisposing factors. CPK should be evaluated prior and during IQIRVO treatment, patients should be advised to report promptly any unexplained muscle symptoms and treatment should be interrupted if increases in CPK or unexplained signs and symptoms of muscle injury are observed[1]

Please refer to the Summary of Product Characteristics for a full summary of side effects

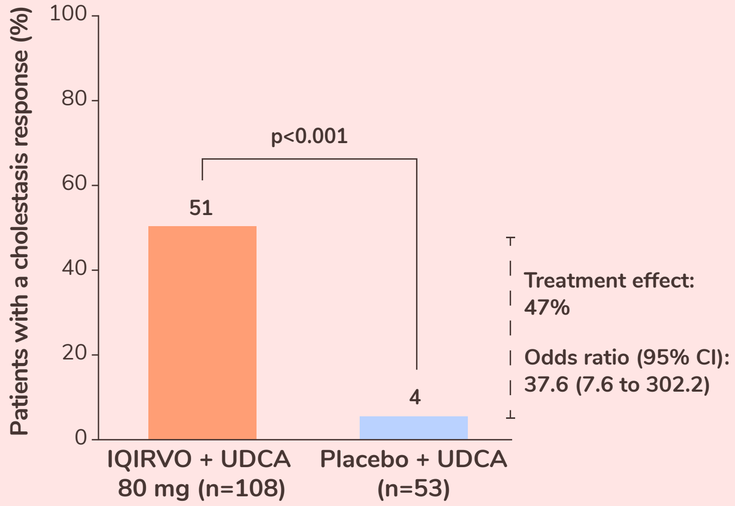
IQIRVO efficacy data

Clinical data supporting use of IQIRVO in patients with PBC.

The clinical efficacy of IQIRVO was evaluated in the phase 3 ELATIVE trial; a randomised, double-blind trial with an open label extension.[1]

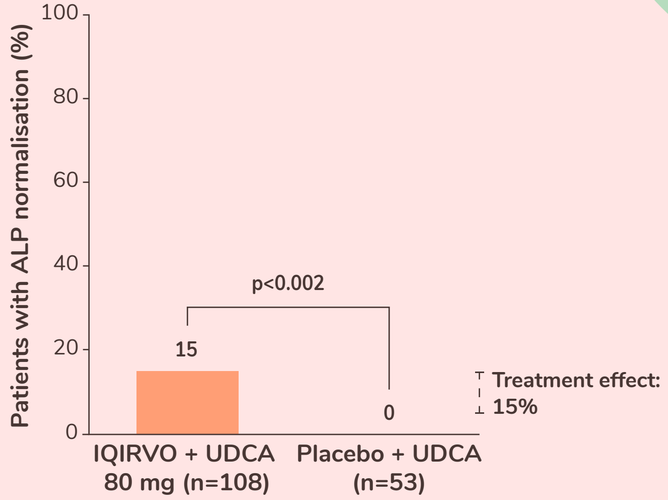
At week 52, 108 participants had been treated with IQIRVO, and 53 with placebo.[1*] The mean ALP level was 322 U/L at baseline.[3]

IQIRVO led to a significant improvement in cholestasis response (primary endpoint):[1*†]



†Cholestasis response defined as: ALP <1.67 x ULN, total bilirubin ≤ULN, and ALP decrease ≥15%

15% of patients receiving IQIRVO also achieved **ALP normalisation‡**, compared with 0 patients receiving placebo:[1,3]



‡Normalisation of ALP at week 52 defined as proportion of participants with ALP ≤1.0. ULN

*Elafibranor 94% received UDCA (102 patients). Placebo 96% received UDCA (51 patients)

IQIRVO pruritus data[3]

IQIRVO may cause a reduction in pruritus impact.

IQIRVO + UDCA demonstrated an observed mean change in pruritus from baseline to Week 52 as measured by PBC WI-NRS in patients with moderate-to-severe pruritus when compared with placebo + UDCA. This result was non-significant.

PBC-40 and 5-Dimensional Itch Scale total scores were reduced with IQIRVO + UDCA compared with placebo + UDCA at Week 52 in patients with moderate-to-severe pruritus at baseline.

Least Squares Mean (95% confidence interval)	IQIRVO 80 mg (n=44)	Placebo (n=22)	Treatment Difference
WI-NRS: Change from baseline through week 52	-1.9 (-2.6, -1.3)	-1.1 (-2.1, -0.2)	-0.8 (-2.0, 0.4)
PBC-40 Itch total score: Change from baseline at week 52	-2.5 (-3.4, -1.6)	-0.1 (-1.6, 1.3)	-2.3 (-4.0, -0.7)
5-D Itch total score: Change from baseline at week 52	-4.2 (-5.6, -2.9)	-1.2 (-3.3, 0.9)	-3.0 (-5.5, -0.5)



IQIRVO safety data

IQIRVO + UDCA is generally well tolerated, with a similar percentage of adverse events when compared with placebo + UDCA.[1,3]

The most common side effects reported were: abdominal pain, diarrhoea, nausea, vomiting (each observed in 11.1% of study participants in the IQIRVO group). All of these were non-serious and mild to moderate in severity.[1]

The most common side effect leading to treatment discontinuation was blood creatine phosphokinase increase (3.7%).[1]

Side effects are listed to the right, grouped by how commonly they occurred in the study group:[1]

Uncommon

(between 1 in 100 and 1 in 1000 people)

Rash pruritic

Blood creatinine increased

Common

(between 1 in 10 and 1 in 100 people)

Headache

Constipation

Cholelithiasis

Myalgia

Increase in blood creatine phosphokinase (CPK) levels

Very common

(more than 1 in 10 people)

Abdominal pain

Diarrhoea

Nausea

Vomiting

References

1. IQIRVO SmPC.

2. European Association for the Study of the Liver. *J Hepatol* 2017;67(1):145-172.

3. Kowdley KV et al. *NEJM* 2023.

4. Tyagi S, et al. *J. Adv. Pharm. Tech. Res* 2011;2:236-240.

ELA-UK-000436 I Date of preparation: August 2026