

Drug Recall

DATE OF RECALL: September 11, 2025

DRUG NAME: Ocaliva® (obeticholic acid)

RECALLING FIRM: Intercept

REASON FOR RECALL: Intercept announced the voluntary withdrawal of Ocaliva (obeticholic acid) tablets following a request from the Food and Drug Administration (FDA) due to safety concerns.

FDA LINK: N/A

OTHER DETAILS: N/A

RECALLED PRODUCT:

Product Description	NDC Number	Lot Number	Expiration Date
Ocaliva (obeticholic acid) 5 mg tablets	69516-0005-30		
Ocaliva (obeticholic acid) 10 mg tablets	69516-0010-30		