Humana.

Drug withdrawal for OCALIVA® (obeticholic acid)

On September 11, 2025, Intercept Pharmaceuticals, Inc. announced its decision to voluntarily withdraw OCALIVA® (obeticholic acid) from the US market. This decision follows a request from the US Food and Drug Administration (FDA) because Ocaliva may increase the risk of serious liver injury in people taking Ocaliva to treat primary biliary cholangitis (PBC). In addition, FDA has placed a clinical hold on all Intercept clinical trials involving obeticholic acid.

Please carefully review the impacted medication and talk to your doctor about it right away.

What This Means for You:

- Contact your doctor or healthcare provider to check if you are impacted and to discuss alternatives.
- To determine if your medication is affected, you should look at the drug name and company name on the label of your prescription. If the information is not on the bottle, you should contact the pharmacy that dispensed the medication.
- Ocaliva will no longer be sold after November 14, 2025.
- If you are not taking Ocaliva, or if your doctor has already told you to stop, you do not need to do anything.
- You can contact the company with any questions regarding this recall by calling Intercept's Patient Support Services (Interconnect) at **1-844-622-4278** (TTY: 711).

Adverse reactions or quality problems experienced with the use of this product may be reported to the Food and Drug Administration's MedWatch Adverse Event Reporting program either online or by regular mail or fax.

- Online: Complete and submit the report: https://www.accessdata.fda.gov/scripts/ medwatch
    - Select Consumer/Patient (FDA Form 3500B)
- Regular mail or fax: Download form at www.fda.gov/media/85598/download
    - Form FDA-3500B: Consumer Voluntary Reporting will automatically download

Note: A reporting form also may be requested by calling **800-332-1088** (TTY:711). Complete and return to the address on the pre-addressed form or submit by fax to **800-FDA-0178 (332-0178)**.

Call If You Need Us

If you have questions about this medicine or the recall, please talk to your doctor or pharmacist.

As your partner in health, we want to make sure that you are informed about issues that may affect your health and overall well-being.

Sources:

- 2024 Drug Safety Communications: *Serious liver injury being observed in patients without cirrhosis taking Ocaliva (obeticholic acid) to treat primary biliary cholangitis,* https://www.fda.gov/drugs/drug-safety-and-availability/2024-drug-safety-communications
- Drug company press release: https://www.interceptpharma.com/about-us/news