COMMUNICATION

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Safety Notification

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members. The clinical team wants to communicate the latest up-to-date drug safety information.

FDA Approves Additional Information in Labeling for Kybella (Deoxycholic Acid) Injection

Warning of Adverse Reactions Associated with Unapproved Use

U.S. Food & Drug Administration Publication Date:

09/15/2026

Drug Indication:

For improvement in the appearance of moderate to severe convexity or fullness associated with submental fat in adults.

Safety Topic:

Kybella (deoxycholic acid) labeling was updated to warn against use outside the submental (under-the-chin) fat area due to the risk of serious neuromuscular and other adverse events. The FDA also added warnings about injection-site nodules and masses, which may persist, require medical intervention, and can occur both within and outside the approved treatment area.

It is for this reason that we are notifying you that on September 15, 2026, the U.S. Food and Drug Administration (FDA) published a safety communication for the following product(s): Kybella (deoxycholic acid).

Reason for Communication

The Food and Drug Administration has approved an additional warning in labeling for Kybella (deoxycholic acid) injection regarding adverse reactions associated with use of the drug outside of the submental fat region (fat under the chin, known as a “double chin”) and recommends against this unapproved use. After the review of FDA Adverse Event Reporting System (FAERS) reports (now known as the FDA Adverse Event Monitoring System) and the medical literature, the FDA determined that when Kybella is administered outside the submental fat region, neuromuscular and other serious adverse events may occur.

The agency has also approved language in the Warnings and Precautions section of labeling about the serious risks of injection site nodules and masses. These newly identified risks are being added to information on other injection site reactions already described in labeling. In this same FAERS review, the agency determined that there is an association between deoxycholic acid injection and reports of injection site nodules (3 cm or smaller) or masses (larger than 3 cm), which may not resolve over time and may require medical intervention. Nodules and masses may occur when patients receive deoxycholic acid injections as indicated in the submental fat region and when patients receive injections of the drug outside the submental fat region.

Pharmacy Required Action

Advise patients to seek medical attention if they experience any adverse events, difficulty swallowing, or serious injection site reactions.

Assess whether the potential benefits of continuing the drug outweigh the potential risks highlighted in this safety communication.

Remember you can report adverse events related to this or any other drug product at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

Complete and submit the MedWatch Online Voluntary Reporting Form online.

Download FDA Form 3500 or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

Additional information can be found at: MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252-ext.219. Our pharmacists will help you.

In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

REFERENCES:
1. U.S. Food and Drug Administration. (2026). FDA Approves Additional Information in Labeling for Kybella (Deoxycholic Acid) Injection Warning of Adverse Reactions Associated with Unapproved Use. Retrieved September 17, 2026, https://www.fda.gov/drugs/drug-safety-communications/fda-approves-additional-information-labeling-kybella-deoxycholic-acid-injection-warning-adverse
2. MedWatch: The FDA Safety Information and Adverse Event Reporting Program- Available at: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda