衞生署藥物辦公室
藥物評審及警戒科
香港九龍觀塘巧明街 100 號
Landmark East 友邦九龍大樓
20 樓 2002-05 室

DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG EVALUATION AND
PHARMACOVIGILANCE DIVISION
Suites 2002-05, 20/F, AIA Kowloon Tower,
Landmark East, 100 How Ming Street,
Kwun Tong, Kowloon, Hong Kong

電話號碼 Tel. No.: (852) 3974 4175
詢問處 Enquiries (852) 3974 4175
傳真號碼 Faxline No.: (852) 2803 4962
本署檔號 OUR REF.:
(來函請敍明此檔案號碼) DH DO DIMC/7-30/1
(IN REPLY PLEASE QUOTE THIS FILE REF.)

16 Sep 2026

Dear Healthcare Professionals,

FDA Approves Additional Information in Labeling for Kybella (Deoxycholic Acid) Injection on Warning of Adverse Reactions Associated with Unapproved Use

Your attention is drawn to the following United States Food and Drug Administration's (FDA) announcement.

What is FDA Doing?

FDA 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. The agency approved this revised labeling after its review of FDA Adverse Event Reporting System (FAERS) reports (now known as the FDA Adverse Event Monitoring System) and the medical literature. In this review, 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.

What Is Kybella (Deoxycholic Acid) Injection?

Kybella (deoxycholic acid) injection was approved in 2015 for improvement in the appearance of moderate-to-severe fullness associated with submental fat in adults. Kybella is not approved for the

treatment of subcutaneous fat outside the submental region and such use is not recommended. A generic deoxycholic acid injection product is also FDA-approved.

What Should Patients Do?

Patients should be aware of serious adverse events that have been reported when Kybella (deoxycholic acid) is injected at sites other than under the chin, including blurred or reduced vision, involuntary eye contractions, muscle and nerve damage and weakness, numbness, and difficulty walking.

Patients should also be aware that injection site nodules and masses have been reported with use of Kybella as indicated (under the chin), as have other adverse events — such as nerve injury around the lower lips, tongue and jaw; difficulty swallowing; bruising; tissue damage; vascular injury; and injection site baldness, ulceration, necrosis (tissue death), and infection — that are already included in labeling.

If patients experience adverse events from using Kybella, they should seek medical attention.

Kybella and a generic deoxycholic acid injection product are the only drugs approved by FDA for improvement in the appearance of moderate-to-severe fullness associated with submental fat. FDA is aware of adverse events reported with the use of unapproved injection lipolysis (fat-dissolving) products and urges people not to use those products. More information is available on the FDA website.

What Should Healthcare Providers Do?

Healthcare providers should review the prescribing information prior to injecting Kybella (deoxycholic acid) injection, including that the drug is not approved for use in areas of the body other than the submental area. Healthcare providers should also be aware that FDA has identified an association between Kybella and reports of injection site reactions, including nodules and masses, which may not resolve over time and may require medical intervention.

Providers should advise patients to seek medical attention if they experience any adverse events, including signs of marginal mandibular nerve paresis (e.g., asymmetric smile, facial muscle weakness), difficulty swallowing, or serious injection site reactions.

What Did FDA Find?

FDA searched the FDA Adverse Event Monitoring System and the medical literature to identify cases of nodules and masses following deoxycholic acid injections that resolved over time or remained unresolved and required medical intervention. FDA also searched for cases describing adverse events with deoxycholic acid injections administered in sites other than the submental fat region.

Since Kybella's approval in 2015, FDA identified 129 cases of adverse events when deoxycholic acid injection was used in areas of the body outside of the approved site (submental region). Some serious adverse events reported with use outside the submental fat region include blurred or reduced vision with periorbital use and muscle or nerve injury including facial paresis and paresthesia.

FDA also identified 117 cases of unresolved nodules (3 cm or smaller) or masses (larger than 3 cm) associated with deoxycholic acid injections. At the time of reporting, unresolved nodules or masses had been present for a mean of 143 days (approximately 5 months). These unresolved nodules or masses have occurred after either initial or subsequent deoxycholic acid injections.

Please refer to the following website in FDA for details:
https://www.fda.gov/drugs/drug-safety-communications/fda-approves-additional-information-labeling-kybella-deoxycholic-acid-injection-warning-adverse

In Hong Kong, there is one registered pharmaceutical product containing deoxycholic acid for injection, namely Belkyra Solution For Injection 20mg/2ml (HK-65660), and is registered by Allergan Hong Kong Limited. It is a prescription-only medicine which is indicated for use in submental fat area only. So far, the Department of Health (DH) has not received any case of adverse drug reaction with regard to deoxycholic acid. In light of the above FDA's announcement, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board of Hong Kong.

Please note that this letter serves as a means for the DH to communicate important new safety information about registered pharmaceutical products with healthcare professionals in Hong Kong and is not intended to serve as guidelines or to replace professional clinical judgement. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Clinical Trials and Pharmacovigilance Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "ADR Reporting": http://www.drugoffice.gov.hk/adr.html. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" (https://www.drugoffice.gov.hk/eps/do/en/healthcare_providers/news_informations/drug_news.html) which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully,

(Clive CHAN)
for Assistant Director (Drug)