Drug recall notice for all Akorn drug products

To assist you in the care of your patients, we would like to alert you to the recall of all Akorn Operating Co. LLC products on April 26, 2023.[1] We recommend you review your medical records and contact all patients for whom you have prescribed this medication to warn them of the recall.

The drug manufacturer, Akorn Operating Co. LLC, is voluntarily recalling these products due to the company declaring bankruptcy on Feb. 23, 2023. The company has ceased all operations. As a result, the Akorn Trustee has initiated a voluntary recall of various within-expiry human and animal products because of the closures and discontinuation of the Quality activities for these products.

The drug products impacted are listed here: www.fda.gov/media/167552/download.

The discontinuation of the Quality program means Akorn will not be able to support or guarantee that these products will meet all intended specifications through the labeled shelf life of the product. While specific risks to patients from use of these adulterated products cannot always be identified or assessed, it is also not possible to rule out patient risks resulting from the use of such products, according to Akorn.

To date, Akorn has received no reports of adverse events related to this recall.

Medications included in this recall
Visit the U.S. Food and Drug Administration (FDA) website at www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/akorn-issues-voluntary-nationwide-recall-various-human-and-animal-drug-products-within-expiry-due for specific details about the recalled medications.

Information for providers:[1]

- We have sent a letter to your CarePlus-covered patients who have had a claim for various Akorn products and asked them to contact their physicians or healthcare providers if their medication is included in the recall and if they have experienced problems that may be related to using these drug products.
- Healthcare providers with questions can contact Akorn at 1-800-932-5676, Monday – Friday, 8 a.m. – 5 p.m., Central time. A qualified medical professional will return the call within one business day.
- Patients may report adverse reactions or quality problems experienced with the use of these products to the FDA's MedWatch Adverse Event Reporting Program online, by regular mail or by fax.
    - **Online:** Complete and submit the report.
        - Select "Consumer/Patient (FDA Form 3500B)."
    - **Regular mail or fax:** Download the form.
        - Complete and submit "Form FDA 3500B – Voluntary Reporting for Consumers" by mail to the address on the form or by fax to 1-800-FDA-0178 (332-0178).

Reference:

1. "Akorn Issues Voluntary Nationwide Recall of Various Human and Animal Drug Products Within Expiry Due to Company Shutdown," U.S. Food and Drug Administration, last accessed April 28, 2023, www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/akorn-issues-voluntary-nationwide-recall-various-human-and-animal-drug-products-within-expiry-due.