Important Drug Recall Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC23-026-CG
May 1st, 2023

FDA announced that Teva Pharmaceuticals USA, has initiated a voluntary nationwide recall of specific lots of various strengths of **FENTANYL Buccal Tablets CII** to the Consumer Level. Teva USA manufactured and labeled these product lots exclusively for Mayne Pharma Inc. under Mayne's label. This recall has been initiated because safety updates were omitted in the Product Insert/Medication Guide (MG) that are provided with these recalled lots.

RECOMMENDATIONS

1. Teva notified its customer, Mayne Pharma Inc. on April 27, 2023, alerting them that the lots were recalled and requesting that they return impacted product. Instructions for returning recalled product and receiving a credit are given in the Recall letter and Consumer Recall letter released by Teva.

2. Consumers with questions or concerns should first consult with their health care provider(s). To report an Adverse Event or Quality Complaint, or if you have Medical Related Questions, please use the following contact information:

   a. **Medical-related Questions or to report an Adverse Event**:
   Contact Medical Information at: 888-483-8279 or USMedInfo@tevapharm.com
   Live calls received: M - F, 9:00 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week.

   b. **Product Quality Complaint-related Questions**:
   Contact Quality Assurance Services: 888-838-2872, option 4
   Live calls received: M - F, 9:00 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs. / day, 7 days/week Review your inventory to identify existence of recalled products.

3. Expect patients to visit your pharmacy to deliver recalled products and prepare your pharmacy staff on how to handle the situation.

MC-Rx Pharmacy Services Department

T. (800) 377-1037
1267 Professional Pkwy, Gainesville, GA 30507
T. (787) 286-6032
Call Box 4908, Caguas, P.R. 00726
MC-Rx.com

FDA U.S. FOOD & DRUG ADMINISTRATION

Teva Initiates Voluntary Nationwide Recall of Specific Lots of FENTANYL Buccal Tablets CII Due to a Labeling Error

Summary:

Company Announcement Date:	**April 27, 2023**
FDA Publish Date:	**April 28, 2023**
Product Type:	**Drugs**
Reason for Announcement:	**Safety updates were omitted in the Product Insert/Medication Guide (MG)**
Company Name:	**Teva Pharmaceuticals USA**
Brand Name:	**Mayne Pharma Inc.**
Product Description:	**FENTANYL Buccal Tablets CII**

Company Announcement

27 April 2023, Parsippany, NJ. Teva Pharmaceuticals USA, has initiated a voluntary nationwide recall of specific lots of various strengths of FENTANYL Buccal Tablets CII to the Consumer Level. Teva USA manufactured and labeled these product lots exclusively for Mayne Pharma Inc. under Mayne's label. This recall has been initiated because safety updates were omitted in the Product Insert/Medication Guide (MG) that are provided with these recalled lots.

The main safety concern is a potential for incomplete information needed by health care providers and patients regarding safe use of the product. Not following, or not being aware of, the omitted safety updates in the Product Insert/Medication Guide (MG) could lead to life-threatening adverse events; although, based on a Health Hazard Assessment conducted by Teva, the likelihood of the harm occurrence is considered remote. To date, Teva has not received any complaints related to the product labeling.

NDC#	Lot	Exp. Date	Strength	Size
51862-634-28	42617828	06/2023	100 mcg	28 Buccal Tablets (4 tablets x 7 cards)
51862-634-28	100020465	01/2024	100 mcg	28 Buccal Tablets (4 tablets x 7 cards)
51862-635-28	100020528	09/2024	200 mcg	28 Buccal Tablets (4 tablets x 7 cards)
51862-635-28	100026699	11/2024	200 mcg	28 Buccal Tablets (4 tablets x 7 cards)
51862-636-28	100020351	11/2024	400 mcg	28 Buccal Tablets (4 tablets x 7 cards)

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NDC#	Lot	Exp. Date	Strength	Size
51862-636-28	100020522	09/2024	400 mcg	28 Buccal Tablets (4 tablets x 7 cards)
51862-636-28	100026700	11/2024	400 mcg	28 Buccal Tablets (4 tablets x 7 cards)
51862-637-28	42617831	06/2023	600 mcg	28 Buccal Tablets (4 tablets x 7 cards)
51862-637-28	42619585	11/2023	600 mcg	28 Buccal Tablets (4 tablets x 7 cards)
51862-637-28	100029649	11/2024	600 mcg	28 Buccal Tablets (4 tablets x 7 cards)
51862-638-28	42617832	06/2023	800 mcg	28 Buccal Tablets (4 tablets x 7 cards)
51862-638-28	42619530	08/2023	800 mcg	28 Buccal Tablets (4 tablets x 7 cards)
51862-638-28	100020532	11/2024	800 mcg	28 Buccal Tablets (4 tablets x 7 cards)

The approved product's indications are: Fentanyl buccal tablet is an opioid agonist indicated for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking, for one week or longer, around-the-clock medicine consisting of at least 60 mg of oral morphine per day, at least 25 mcg per hour of transdermal fentanyl, at least 30 mg of oral oxycodone per day, at least 8 mg of oral hydromorphone per day, at least 25 mg oral oxymorphone per day, at least 60 mg of oral hydrocodone per day, or an equianalgesic dose of another opioid. Patients must remain on around-the-clock opioids while taking fentanyl buccal tablet.

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Product Quality Complaint-related Questions:

Contact Quality Assurance Services: **888-838-2872**, option 4
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Adverse events or other problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax. Complete and submit the report Online

Regular Mail or Fax: Download form 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.**

This recall was made with the knowledge of the Food and Drug Administration. Teva will continue to partner with, and regularly update, all relevant stakeholders, including regulatory authorities, to resolve this situation.

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