COMMUNICATION

COM-2023-023

08
MAY
2023

URGENT
PLEASE
REVIEW

Recall Notification

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate you the latest up-to-date drug recall information.

U.S. Food & Drug Administration Publication Date:

04/28/2023

Drug Information:

National Drug Code

Refer to Table 1 for details.

Product Description

FENTANYL BUCCAL TABLETS 100MCG, 200MCG, 400MCG, 600MCG and 800MCG.

Lot Number

Refer to Table 1 for details.

Expiration Date

Refer to Table 1 for details.

Company:

TEVA PHARMACEUTICALS USA

QUESTIONS

Medical-related Questions or to Report an Adverse Event: Contact Medical Information at: 888-483-8279 Monday – Friday from 9:00 a.m. to 5:00 p.m. ET or email at USMedInfo@tevapharm.com

Product Quality Complaint-related Questions: Contact Quality Assurance Services at 888-838-2872, option 4, Monday – Friday from 9:00 a.m. to 5:00 p.m. ET.

Fentanyl Buccal Tablets CII

It is for this reason that we are notifying you that on 04.28.2023 the US Food and Drug Administration published a drug recall for the following product(s): Fentanyl buccal tablets, CII 100mcg, 200mcg, 400mcg, 600mcg and 800mcg.

Pharmacy Required Action:

Identify if the product is in inventory and immediately stop using and dispensing it. Please contact Teva's product recall processor Inmar at 855-246-5024 or email Inmar at rxrecalls@inmar.com to obtain instructions for returning the recalled products.

Advise patients that they should not discontinue using the medication without contacting their healthcare provider. Patients experiencing any problem while taking or using this product must contact their physician.

Reason for Recall:

Teva Pharmaceuticals USA has initiated a voluntary nationwide recall of specific lots of various strengths of fentanyl buccal tablets CII to the consumer level. This recall has been initiated because safety updates were omitted in the Product Insert/Medication Guide that are provided with these recalled lots.

Teva's Health Hazard Assessment concluded that the main safety concern is a potential for incomplete information needed by healthcare providers and patients regarding safe use of the product. Not being aware of the omitted safety updates in the Product Insert could lead to life-threatening adverse events. To date, Teva has not received any complaints related to the product labeling.

Table 1, included in this notification, provides a complete list of the recalled NDCs.

Table 1. Specific Lots of Various Strengths of Fentanyl Buccal Tablets CII Being Recalled

Table 1 Specific Lots of Various Strengths of FENTANYL Buccal Tablets CII Being Recalled				
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)
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)

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. 220. Our pharmacists will help you.

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

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Pharmacy Benefit Management
Expires 12/01/2025

REFERENCES:

1. U.S. Food and Drug Administration. (2023). Teva Initiates Voluntary Nationwide Recall of Specific Lots of FENTANYL Buccal Tablets CII Due to a Labeling Error. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/teva-initiates-voluntary-nationwide-recall-specific-lots-fentanyl-buccal-tablets-cii-due-labeling
2. MedWatch: The FDA Safety Information and Adverse Event Reporting Program. https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda