Teva – Recall of fentanyl buccal tablets

- On April 28, 2023, the FDA announced a consumer level recall of certain lots of Teva's fentanyl buccal tablets because safety updates were omitted in the Product Insert/Medication Guide that are provided with these recalled lots.
    - Clinical Services identified potentially impacted members and will send notifications to the members and their prescribers.
    - The member letter advises members to contact their healthcare provider or pharmacy for a replacement.
- The fentanyl buccal tablets are manufactured by Teva and exclusively labeled for Mayne Pharma. The recalled lots were distributed August 2020 through January 2022.

Product Description	NDC#	Lot# (Expiration Date)
Fentanyl 100 mcg buccal tablets (4 tablets x 7 cards)	51862-634-28	42617828 (6/23); 100020465 (1/24)
Fentanyl 200 mcg buccal tablets (4 tablets x 7 cards)	51862-635-28	100020528 (9/24); 100026699 (11/24)
Fentanyl 400 mcg buccal tablets (4 tablets x 7 cards)	51862-636-28	100020351 (11/24); 100020522 (9/24); 100026700 (11/24)
Fentanyl 600 mcg buccal tablets (4 tablets x 7 cards)	51862-637-28	42617831 (6/23); 42619585 (11/23); 100029649 (11/24)
Fentanyl 800 mcg buccal tablets (4 tablets x 7 cards)	51862-638-28	42617832 (6/23); 42619530 (8/23); 100020532 (11/24)

- 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.
- 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 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.

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- Contact Teva by phone at **1-888-483-8279** or by email at **USMedInfo@tevapharma.com** for questions regarding this recall.