PHARMACIST'S GUIDE FOR DISPENSING

FENTORA® BUCCAL TABLETS

This document has been reviewed and approved by the Ministry of Health on February 2023

FENTORA® (fentanyl buccal tablet)

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INTRODUCTION

This guide is designed to help you understand the proper dispensing of FENTORA® (fentanyl buccal tablets) for patients experiencing breakthrough cancer pain (BTcP). Please read this guide carefully before dispensing FENTORA® and keep it for future reference. The pharmacist dispensing checklist should be reviewed before dispensing the product. Encourage patients to communicate all medication-related issues to their prescriber.

Note: FENTORA® buccal tablets should only be initiated/supervised by physicians who are experienced, knowledgeable and qualified in the management of cancer pain using opioid therapy. Special care should be taken when patients transition from the hospital to home-based care. Pharmacists play an important role in supervising the provision and use of FENTORA®.

The following materials are also available:

» A Patient/Carer Guide to the safe use of FENTORA® Buccal Tablets

» A Physician's Guide for Prescribing FENTORA®

This Pharmacist's Guide (and the other materials listed above) can be viewed or downloaded from the Israeli Ministry of Health website:

https://www.gov.il/he/Departments/DynamicCollectors/patient-safety-information

REPORTING SIDE EFFECTS

Side effects can be reported to the Ministry of Health using the online form for side effect reporting that is found in the Ministry of Health homepage:

www.health.gov.il

or via the link:

https://sideeffects.health.gov.il

or through the marketing authorization holder:

Safety.Israel@Teva.co.il

FENTORA® (fentanyl buccal tablet)

WHAT IS FENTORA®?

FENTORA® for the treatment of cancer breakthrough pain

FENTORA® is an opioid analgesic. FENTORA® is indicated for the treatment of breakthrough pain (BTcP) in adults with cancer who are already receiving maintenance opioid therapy for chronic cancer pain.[1]

FENTORA® is suitable for adult patients with BTcP who have been receiving maintenance opioid therapy for at least a week, consisting of:

- At least 60 mg of oral morphine daily, **or**
- At least 25 micrograms of transdermal fentanyl per hour, **or**
- At least 30 mg of oxycodone daily, **or**
- At least 8 mg of oral hydromorphone daily, **or**
- An equianalgesic dose of another opioid[1]

Breakthrough Cancer Pain (BTcP)

- BTcP is when a patient suffers temporary (non-permanent) pain episodes that are of greater intensity than their background pain or the pain they normally experience during maintenance opioid treatment[2, 3]

BTcP is usually of medium to high intensity. Episodes start quickly and are short-lived (about 30 minutes long).[3] Continuous cancer pain is treated with a number of management strategies, including around-the-clock opioids, other analgesics, and non-pharmacological approaches, but BTcP generally requires rapid- or short-acting opioids.[3]

HOW IS FENTORA® USED?

Left untreated, BTcP can have serious negative effects on a patient's quality of life. As a pharmacist, you should talk to patients before dispensing FENTORA® to ensure they understand how to use FENTORA® correctly, according to the Summary of Product Characteristics (SmPC) and Package Leaflet (PL):

1 Buccal tablet	One tablet of FENTORA® per BTcP episode, with the possibility of taking a second FENTORA® tablet of the same strength after at least 30 minutes, if BTcP is not relieved. Breakthrough pain episodes may vary in intensity and the required FENTORA® dose might increase over time due to progression of the underlying cancer disease. In these cases, a second tablet of the same strength may be used. If a second tablet of FENTORA® was required for several consecutive times, the usual maintenance dose is to be readjusted[1]
4 Hours	It is important to explain to the patient that there should generally be at least 4 hours between each treatment of a BTcP episode, highlighting the risks associated with more frequent use[1]
No more than 4 tablets	Dose readjustment of the background opioid therapy may be required if patients consistently present with more than four BTcP episodes per 24 hours[1]

Please note that FENTORA® buccal tablet is not interchangeable with other Fentanyl products.

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WARNINGS

Overdose

Unintentional exposure to FENTORA® is considered a medical emergency and a potentially life-threatening event. Make sure that you and your staff know the signs of fentanyl overdose/toxicity and the need for urgent medical attention.

The most serious signs of overdose/toxicity are:

- Altered mental status
- Loss of consciousness
- Coma
- Hypotension
- Respiratory depression, respiratory distress, and respiratory failure, which have resulted in death
- Cases of Cheyne-Stokes respiration have been observed in case of fentanyl overdose, particularly in patients with history of heart failure

Any of these symptoms require immediate medical attention, as these can lead to death without proper medical treatment. Patients or their carers should therefore immediately call the **Magen David Adom emergency number (101)** in the event of an overdose or the appearance of the symptoms mentioned.

- Please ensure that patients and carers are made aware of the signs of fentanyl overdose/toxicity described above, understand the potential seriousness and have been adequately instructed on what to do in an emergency
- Watch for signs that the patient may not be using the product as prescribed, and be aware of the serious risk of misuse, abuse, medication errors, overdose, and addiction
- Ensure that the patient is aware of the potential for misuse, abuse, overdose, and addiction associated with FENTORA®

SAFETY, STORAGE AND DISPOSAL

Remind the patient of the following important storage instructions:

- FENTORA® should only be handled by patients or their carers. Please advise the patient to never let anyone else handle or use the product
- Store FENTORA® in the original package in order to protect from moisture. The tablet should not be stored once removed from the blister package as the tablet integrity cannot be guaranteed and a risk of accidental exposure to a tablet can occur
- Please draw the attention of patients and their cares to the danger if children are exposed to FENTORA®
- Please ensure patients understand that in order to prevent theft, diversion (misuse for illegal purposes), and other misuse of the drug, they should store FENTORA® in a suitably secure place. Fentanyl, the active constituent of FENTORA®, is a target for people who abuse narcotic medicines or other street drugs and therefore the storage instructions must be closely followed[1]

Please counsel patients on these additional safety and disposal instructions:

- Instructions for opening the blister pack (Package Leaflet)
- Appropriate disposal of FENTORA® buccal tablets - any used or unused but no longer required medicinal product or waste material should be disposed of in accordance with local requirements[1]

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RISKS ASSOCIATED WITH OFF-LABEL USE OF FENTORA®

Importance of preventing off-label use

» The use of FENTORA® in any way other than that described in the approved SmPC is considered off-label use. If you are concerned that off-label use may be taking place, please contact the prescriber to discuss your concerns

» Off-label use can take many forms, including prescribing:

- For an indication other than BTcP in cancer patients, including any other type of pain, acute or chronic
- If the patient is not receiving maintenance opioid therapy for their background pain
- More frequent dosing than licensed
- To someone who is under 18-years old

» Each of these off-label uses poses a **risk** to the patient. At worst, it can lead to **addiction, overdose, and death**. Side effects are generally increased with off-label use

Medication errors are particularly important to avoid when prescribing an opioid

Medication errors include:

» Unintentional drug prescribing error

» Drug administration error

» Drug dispensing error

» Incorrect dosage administered

» Use of an incorrect route of administration

In order to minimize the risk of medication errors, all FENTORA® labels are color-coded differently for each of the strengths of action:

100 mcg- blue | 200 mcg- orange | 400 mcg- green | 600 mcg- pink | 800 mcg- yellow

RISKS ASSOCIATED WITH "OPIOID USE DISORDER" (OUD)

What is OUD?

- OUD is a "problematic pattern of opioid use that leads to clinically significant impairment or exposure" (DSM-5)[4]
- The diagnostic criteria for OUD include taking too much of the opioid, inability to cut down use, craving, negative effects on work, home, or social life, use in hazardous situations, use despite knowledge of negative effects, tolerance, and withdrawal[4]
- The severity of OUD is determined by the number of diagnostic criteria that the patient meets[5]
- Patients will require monitoring for signs of drug-seeking behaviour (e.g. too-early requests for prescriptions). Monitoring also should include a review of prescription frequency for concomitant opioids and psychoactive drugs (such as benzodiazepines)

Who is at risk of OUD?

The following patients may have an increased risk of developing OUD:

- Patients who switch from hospital-based to home care
- Patients with a personal or family history (parents or siblings) of substance use disorder, including alcohol abuse[6]
- Patients who smoke
- Patients with other medical challenges
- Personal history of other mental health problems (e.g. severe depression, anxiety, and personality disorders)
- Personal history of other mental health problems (e.g. severe depression, anxiety, and personality disorders)

It is important to pay careful attention to the signs of OUD, as detection will ultimately help the patient.
For example, tolerance (the need for more drugs to achieve the same effect) and withdrawal are criteria associated with OUD. A patient with withdrawal symptoms may complain of nausea and vomiting, anxiety, insomnia, hot and cold flushes, sweating, muscle cramps, watery discharge from the eyes and nose, and/or diarrhea.[7]

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MOST IMPORTANTLY

If you believe that a patient might have an issue with their treatment, discuss your concerns immediately with the patient's prescribing physician. Encourage the patient to regularly talk to their doctor about how their treatment is going. Report any known off-label use, diversion, misuse, abuse, addiction, and overdose via the Ministry of Health homepage:

www.health.gov.il

or via the link:

https://sideeffects.health.gov.il

or through e-mail to the marketing authorization holder:

safety.israel@teva.co.il

MORE INFORMATION

Teva Israel Ltd. P.O.B 3190 124 Dvora HaNevi'a St. Tel Aviv, Israel. Phone: 1-800-805-005

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CHECKLIST FOR DISPENSING FENTORA®

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No.	Description	Done
1	Ensure that all the criteria of the approved indication are fulfilled. FENTORA® should only be prescribed for breakthrough pain (BTcP) in adults with cancer who are already receiving maintenance opioid therapy for chronic cancer pain. If you are unsure about a difference between the label and a prescriber's request, please contact the prescriber for clarification	☐
2	Give the patient and/or carer instructions on how to use the buccal tablets	☐
3	Make sure the patient/carer reads the Package Leaflet inside the FENTORA® package	☐
4	Supply the patient/carer with the FENTORA® Patient/Carer guide and explain the use of the dose monitoring card	☐
5	Explain the risks of using more than the recommended amount of FENTORA®	☐
6	Advise the patient/carer of signs of fentanyl overdose and the need for immediate medical assistance	☐
7	Explain secure storage and the need to keep FENTORA® out of the reach and sight of children	☐
8	Explain the correct process for disposal of FENTORA®	☐
9	Encourage the patient/carer to discuss their maintenance opioid therapy, BTcP, and the patient's use of opioids with their doctor	☐

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