Pharmacist's guide for dispensing Effentora® (fentanyl) buccal tablets

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, www.hpra.ie.

Adverse events may also be reported to Teva Pharmaceuticals Ireland *via* email to medinfo@tevauk.com or *via* phone on +44 (0) 207 540 7117.

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INTRODUCTION

This guide is designed to help you understand the proper dispensing of EFFENTORA® (fentanyl buccal tablets) for patients experiencing breakthrough cancer pain.

Please read this guide carefully before dispensing EFFENTORA® 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: EFFENTORA® 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 EFFENTORA®.

The following materials are also available:

- A Patient/Carer's Guide to the safe use of EFFENTORA® buccal Tablets
- A Prescriber's Guide for prescribing EFFENTORA®

Please ensure that you familiarise yourself with the Patient/Carer Guide before providing it to patients. You must complete the Pharmacist Checklist for dispensing EFFENTORA® for each patient (See page 10)

This Pharmacist's Guide (and the other materials listed above) can be viewed or downloaded from the Health Products Regulatory Authority Website at: https://www.hpra.ie (enter 'EFFENTORA' in Find a Medicines Search Area. Click *'EdM' under the 'Documents' column for the relevant EFFENTORA product).

*For a full list of medicines that have Educational Materials use the advanced search option and click on 'Only Medicines with Educational Materials'

Reporting Side Effects

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WHAT IS EFFENTORA®?

EFFENTORA® for the treatment of breakthrough pain

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

EFFENTORA® is suitable for adult patients with breakthrough pain who have been receiving maintenance opioid therapy for 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 Pain

Breakthrough pain is a transitory exacerbation of pain that occurs on a background of otherwise controlled persistent pain.

HOW IS EFFENTORA® USED?

As a pharmacist, you should talk to patients before dispensing EFFENTORA® to ensure they understand how to use EFFENTORA® correctly, according to the Summary of Product Characteristics (SmPC) and Package Leaflet (PL):

1 buccal tablet

One tablet of EFFENTORA® per breakthrough pain episode, with the possibility of taking a second EFFENTORA® tablet of the same strength after at least 30 minutes, if breakthrough pain is not relieved.

Breakthrough pain episodes may vary in intensity and the required EFFENTORA® 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 EFFENTORA® 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 breakthrough pain 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 breakthrough pain episodes per 24 hours.[1]

Method of administration

Effentora buccal tablets are for oromucosal use. When you place a tablet in your mouth, it dissolves and the medicine is absorbed through the lining of your mouth, into the blood system. Taking the medicine in this way allows it to be absorbed quickly to relieve your breakthrough pain.

Effentora tablet once exposed to moisture utilises an effervescent reaction to deliver the active substance. Therefore patients should be instructed not to open the blister until ready to place the tablet in the buccal cavity.

Opening the blister package

Patients should be instructed NOT to attempt to push the tablet through the blister because this could damage the buccal tablet. The correct method of releasing the tablet from the blister is:

One of the blister units should be separated from the blister card by tearing it apart at the perforations. The blister unit should then be flexed along the line printed on the backing foil where indicated. The backing foil should be peeled back to expose the tablet. Patients should be instructed not to attempt to crush or split the tablet.

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.

HOW IS EFFENTORA® USED?

Tablet administration

Patients should remove the tablet from the blister unit and immediately place the entire Effentora tablet in the buccal cavity (near a molar between the cheek and gum). The Effentora tablet should not be sucked, chewed or swallowed, as this will result in lower plasma concentrations than when taken as directed. Effentora should be placed and retained within the buccal cavity for a period sufficient to allow disintegration of the tablet which usually takes approximately 14-25 minutes

Alternatively, the tablet could be placed sublingually. After 30 minutes, if remnants from the Effentora tablet remain, they may be swallowed with a glass of water. The length of time that the tablet takes to fully disintegrate following oromucosal administration does not appear to affect early systemic exposure to fentanyl.

Patients should not consume any food and drink when a tablet is in the buccal cavity. In case of buccal mucosa irritation, a change in tablet placement within the buccal cavity should be recommended.

Please note that EFFENTORA® buccal tablets are not interchangeable with other Fentanyl products.

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 minimise the risk of medication errors, all EFFENTORA® labels are color-coded differently for each of the strengths of action as follows.

- 100 mcg – Blue
- 200 mcg - Orange
- 400 mcg – Green
- 600 mcg – Purple

OVERDOSE

Repeated use of EFFENTORA® may lead to Opioid Use Disorder (OUD). Abuse or intentional misuse of EFFENTORA® may result in overdose and/or death. Off-label use (e.g. use in children or in patients without maintenance opioid therapy) and medication error (e.g. accidental exposure to EFFENTORA®) may also result in overdose.

The symptoms of fentanyl 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 **emergency number (112 or 999)** 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 EFFENTORA®.

SAFETY, STORAGE AND DISPOSAL

Safety, Storage and disposal

Remind the patient of the following important storage instructions:

- EFFENTORA® should only be handled by patients or their carers. Please advise the patient to never let anyone else handle or use the product.
- Please draw the attention of patients and their carers to the danger if children are exposed to EFFENTORA®.
- Please ensure patients understand that in order to prevent theft, diversion (misuse for illegal purposes), and other misuse of the drug, they should store EFFENTORA® in a suitably secure place. Fentanyl, the active constituent of EFFENTORA®, 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 EFFENTORA® 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]

RISKS ASSOCIATED WITH OFF-LABEL USE OF EFFENTORA®

Importance of preventing off-label use

- ➔ The use of EFFENTORA® 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 breakthrough pain 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.

RISKS ASSOCIATED WITH "OPIOID USE DISORDER" (OUD)

- Repeated use of EFFENTORA® may lead to opioid use disorder (OUD). Abuse or intentional misuse of EFFENTORA® may result in overdose and/or death.
- The risk of developing OUD is increased in patients with a personal or a family history (parents or siblings) of substance use disorders (including alcohol use disorder), in current tobacco users or in patients with a personal history of other mental health disorders (e.g. major depression, anxiety and personality disorders).
- Patients will require monitoring for signs of drug-seeking behaviour (e.g. too early requests for prescriptions). Monitoring should also include a review of prescription frequency for concomitant opioids and pyschoactive drugs (such as benzodiazepines).

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.[2]

Patients/carers should be informed of the risks of abuse and dependence and informed of the need for periodic review by their doctor. If you believe that a patient might have an issue with their treatment or if OUD is recognised, discuss your concerns immediately with the patient's prescribing doctor.

Report any known off-label use, diversion, misuse, abuse, addiction, and overdose via HPRA Pharmacovigilance, www.hpra.ie.

Adverse events should also be reported to Teva Pharmaceuticals Ireland via email to medinfo@tevauk.com or via phone on +44 (0) 207 540 7117.

CHECKLIST FOR DISPENSING EFFENTORA®

- [ ] Ensure that all the criteria of the approved indication are fulfilled. EFFENTORA® should only be prescribed for breakthrough pain 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
- [ ] Give the patient and/or carer instructions on how to use the buccal tablets
- [ ] Make sure the patient/carer reads the Package Leaflet inside the EFFENTORA® package
- [ ] Supply the patient/carer with the EFFENTORA® Patient/Carer guide and explain the use of the dose monitoring card
- [ ] Explain the risks of using more than the recommended amount of EFFENTORA®
- [ ] Advise the patient/carer of signs of fentanyl overdose and the need for immediate medical assistance
- [ ] Explain secure storage and the need to keep EFFENTORA® out of the reach and sight of children

Teva Pharmaceuticals Ireland.
Digital Office Centre Swords, Suite 101-103, Balheary Demesne, Balheary Road, Swords, Co. Dublin, K67E5AO, Ireland

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