

Patient/carer's guide to the safe use of Effentora® (fentanyl) buccal tablets

Please also refer to the Package Leaflet for
EFFENTORA® (fentanyl citrate) Buccal Tablets

Reporting Side Effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via HPRC Pharmacovigilance, Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

Table of Contents

Introduction	3
Reporting Side Effects	
What is EFFENTORA®? How do I use it?	4
What do I need to know about the use of EFFENTORA®?	5
How should I store EFFENTORA®?	6
How to use EFFENTORA® buccal tablets?	7
Cancer and Pain	9
What is special about cancer pain?	
What is breakthrough pain?	
How do I know if I have breakthrough pain?	
What happens if I have breakthrough pain?	
EFFENTORA®: RISKS OF ABUSE, MISUSE, ADDICTION, OVERDOSE AND DEATH	10
Overdose	11
Note for Carers	12
Keep track of how many doses you are taking	13
Dose monitoring card	14

INTRODUCTION

Dear Patient,

Your doctor has prescribed EFFENTORA® buccal tablets. This guide is intended to help you (or your carer) familiarise yourself with important information related to the treatment of your cancer breakthrough pain, as well as the correct application and risks of the buccal tablets.

Please make sure you have read the guide carefully before using EFFENTORA® and keep it for future reference.

EFFENTORA® should only be used if you/your carer has received the proper information regarding the use of the drug and the safety precautions.

In case of any questions, always refer to your doctor or pharmacist.

Reporting Side Effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

WHAT IS EFFENTORA®? HOW DO I USE IT?

EFFENTORA® contains fentanyl, which is a strong pain-relieving medicine known as an opioid. EFFENTORA® is used for adults with cancer suffering from breakthrough pain.³ Breakthrough pain is a pain that feels worse than the background pain you may suffer from most of the time, even though you are taking around the clock opioid pain-relieving medicines.

Only use EFFENTORA® if you:

1. are 18 years of age or older and have cancer, **AND**
2. are already being treated with opioids for background cancer pain every day on a regular schedule, for at least a week, **AND**
3. are suffering with another type of cancer pain that is temporary and feels worse than your background cancer pain, **AND**
4. your doctor or pharmacist have taught you how to use EFFENTORA®.

If even one of these points **does not** apply to you, talk to your doctor. Ask your doctor or pharmacist if you have any questions or concerns about EFFENTORA®.

Important: *Keep using the opioid pain medicine you take for your persistent (around the clock) cancer pain during your EFFENTORA® treatment. Do not use EFFENTORA® to treat any type of pain that you do not think is related to your cancer, such as short-lasting headaches, muscle pains or toothaches.*

What do I need to know about the use of EFFENTORA®?

The initial dose of Effentora should be 100 micrograms, titrating upwards as necessary through the range of available tablets strengths.

It is important that you follow your doctor's advice on how to use EFFENTORA®.

- 1 Tablet** Use one tablet of EFFENTORA® for an episode of breakthrough pain as a general rule. If your breakthrough pain is not relieved after 30 minutes, use only one more tablet of EFFENTORA® during the initial dose-readjustment period.
- 4 Hours** Wait at least 4 hours before treating another episode of breakthrough pain with EFFENTORA®.
- No more than 4 Tablets** You must let your doctor know immediately if you are using EFFENTORA® more than four times per day.

If you feel that you need to use EFFENTORA® more often, consult your doctor for advice. They may need to change your other pain medicines.

Do not change doses of EFFENTORA® or your other pain medicines on your own. Any change in dosage must be prescribed and monitored by your doctor. If you are not sure about the right dose, or if you have questions about using EFFENTORA®, you should contact your doctor.

Important:

1. EFFENTORA® is not the same as other fentanyl products you may have used. Do not swap or change between EFFENTORA® and other fentanyl products. Use EFFENTORA® only as directed by your doctor.
2. EFFENTORA® is available in 100 mcg, 200 mcg, 400 mcg and 600 mcg different dose strengths. Each strength has a different colour code as follows.
 - 100 mcg – Blue
 - 200 mcg - Orange
 - 400 mcg – Green
 - 600 mcg – Purple
3. You and your doctor may have tried different doses of EFFENTORA® to determine the effective dose for you. It is important that you use only the dose strength that your doctor has prescribed.

How should I store EFFENTORA®?

- ➔ Do not use EFFENTORA® after the expiry date shown on the package label and the carton. The expiry date refers to the last day of that month.
- ➔ EFFENTORA® is a very strong pain-relieving medicine and could be life-threatening if taken accidentally by a child. EFFENTORA® must be kept out of the sight and reach of children.
- ➔ Store in the original package in order to protect from moisture.
- ➔ Contact your doctor or pharmacist if you have any questions about the storage of EFFENTORA®.
- ➔ Do not dispose of or throw away any medicines via waste water or in household waste. Ask your pharmacist how to throw away medicines you no longer use.

Important: *Some people abuse opioids such as EFFENTORA®. Make sure that only you or your responsible carers handle or have access to your EFFENTORA®.*

How to use EFFENTORA® buccal tablets:

1. Peel it

- ➔ Open the blister only when you are ready to use the tablet. The tablet must be used immediately once removed from the blister.
- ➔ Separate one of the blister units from the blister card by tearing apart at the perforations.
- ➔ Bend the blister unit along the line where indicated.
- ➔ Peel the blister backing to expose the tablet (as shown in Figure 1). Do NOT attempt to push the tablet through the blister, because this can damage the tablet.



Figure 1

2. Place it

- Remove the tablet from the blister unit and **immediately** place the entire tablet near a molar tooth between the gum and the cheek (as shown in Figure 2). Sometimes, your doctor may tell you to place the tablet under your tongue instead.
- Do not attempt to crush or split the tablet.



Figure 2

- Do not bite, suck, chew, or swallow the tablet, as this will result in less pain relief than when taken as directed.

3. Feel it

- The tablet should be left between the cheek and gum until dissolved, which usually takes approximately 14 to 25 minutes.
- You may feel a gentle bubbling sensation between your cheek and gum as the tablet dissolves.
- In case of irritation, you may change the placement of the tablet on the gum.
- After 30 minutes, if pieces of the tablet remain, they may be swallowed with a glass of water.

CANCER AND PAIN

What is breakthrough pain?

Some people with cancer have constant pain, which is called background pain. Your doctor will prescribe medication to keep this pain at about the same level over time.¹

Breakthrough pain is a pain that feels worse than the background pain you may feel most of the time. You may not know when to expect this pain and this can keep you from doing what you need or want to do.

How do I know if I have breakthrough pain?

Breakthrough pain is usually:²

- ➔ Moderate to severe.
- ➔ Comes on quickly (it can take just a few minutes for the pain to reach its peak).
- ➔ Relatively short-lived (it may last only around 30 minutes).

If you have pain that is not controlled by your current medications, tell your doctor. You may be experiencing breakthrough pain, or your doctor may need to check if the medications you are taking for background pain are still right for you.

What happens if I have breakthrough pain?

People with breakthrough pain often need medicines called short-acting opioids, also known as fast-acting or rapid-onset opioids. They act quickly to provide relief, and are used in addition to the medicines taken to treat background pain.²

EFFENTORA® is an example of a rapid-onset opioid used to treat breakthrough pain. It is only suitable for adults who are already taking opioids for the treatment of background cancer pain.³

EFFENTORA®: RISKS OF ABUSE, MISUSE, ADDICTION, OVERDOSE AND DEATH

A statement on the outer packaging of EFFENTORA® includes a warning on the risk of addiction as follows:

**Can cause addiction
Contains opioid**

Talk to your doctor or pharmacist if you have any questions about the use or possible side effects of EFFENTORA® buccal tablets.

Your doctor may need to check you more closely if:

- You or anyone in your family have ever abused or been dependent on (addicted to) alcohol, other medicines or illegal drugs.
- You are a smoker.
- You have ever had problems with your mood (depression, anxiety or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

Other points to note

- Repeated use of EFFENTORA® may lead to dependence (addiction) and abuse which may result in life-threatening overdose. If you have concern that you may become addicted to EFFENTORA®, it is important that you consult your doctor.
- Do not drink alcohol while using EFFENTORA®. It can increase the chances of getting serious side effects including death.
- Do not use more than two tablets to treat any single episode of breakthrough pain. Once a dose is found that effectively controls your pain, do not use more than four EFFENTORA® tablets each day. You must let your doctor know immediately if you are using EFFENTORA® more than four times per day.

Overdose

Do not change doses of EFFENTORA® or your other pain medicines on your own. Any change in dosage must be prescribed and monitored by your doctor.

If you are not sure about the right dose, or if you have questions about taking this medicine, you should contact your doctor.

- ➔ A serious side effect of EFFENTORA® is slow and/or shallow breathing. This can occur if your EFFENTORA® dose is too high or if you take too much (overdose).
- ➔ If you feel very dizzy, very sleepy or have slow or shallow breathing, remove the EFFENTORA® buccal tablet from your mouth and seek immediate medical assistance.

How do I know if I should worry about addiction?

You might be worried that you will become addicted to opioids. This is a common fear. Talk to your doctor or pharmacist about your concerns.

Some signs that there may be problems with the use of opioids are:

- ➔ You take more of the opioid than your doctor prescribed.
- ➔ You want to stop taking it, but feel like you can't.
- ➔ You crave the opioid.
- ➔ The use of the opioid is affecting your work, home, or social life.⁴

If you notice any of these signs, talk to your doctor.

How to best reduce your risk of having a problem with abuse of EFFENTORA®:

1. Use EFFENTORA® exactly as prescribed.
2. Talk to your doctor immediately if your pain is not under control or if you have concerns about your symptoms or medications.

Tell your doctor or pharmacist if you have any concerns or questions about your use of opioids. If you have any urgent concerns, contact the emergency numbers provided to you and seek medical help.



A note for carers: To help minimise any potential side effects of treatment with EFFENTORA®, talk to the doctor or medically trained support staff. Please also read the Package Leaflet that comes in the EFFENTORA® packaging.

For a electronic version of this guide and other helpful materials, see the Health Products Regulatory Authority (HPRA) 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).

KEEP TRACK OF HOW MANY DOSES YOU ARE TAKING

The dose monitoring card provided below is intended to help you keep track of your use of EFFENTORA®. If you have any questions about your treatment with EFFENTORA®, please talk to your treating doctor.

Every time you use your EFFENTORA® buccal tablet, make sure you or your carer fills out the card. Remember to contact your doctor long before you need to get a new prescription.

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DOSE MONITORING CARD

	Date	Time	Strength of EFFENTORA® Tablet	Number of Tablets
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