

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

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* the Yellow Card Scheme at <https://yellowcard.mhra.gov.uk> or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

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INTRODUCTION

Dear Patient

Your doctor has prescribed EFFENTORA® buccal tablets. This guide is intended to help you familiarise yourself with important information related to the treatment of your cancer breakthrough pain, as well as the correct application of the buccal tablets. Please make sure you have read the guide carefully before using EFFENTORA® and keep it for future reference.

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* the Yellow Card Scheme at <https://yellowcard.mhra.gov.uk> or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

CANCER AND PAIN

What is special about cancer pain?

For people with cancer, pain can affect their quality of life.¹

Pain may be caused by the cancer itself, or it may be caused by cancer treatments or other cancer-related problems.¹ Some pain may have nothing to do with the cancer.

What is breakthrough cancer pain (BTcP)?

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 cancer pain (BTcP) 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 BTcP?

BTcP 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 BTcP, 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 BTcP?

People with BTcP 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 BTcP. It is only suitable for adults who are already taking opioids for the treatment of background cancer pain.³

WHAT IS EFFENTORA®? HOW DO I USE IT?

EFFENTORA® is a strong pain-relieving medicine known as an opioid for adults suffering from BTcP.³ BTcP 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, **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:

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®?

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 1 more tablet of EFFENTORA® during this dose-readjustment period.
- 4 Hours** Wait at least 4 hours before treating another episode of BTcP 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.

Your doctor may change the treatment for your background cancer pain; once your background cancer pain is controlled, your doctor may need to change the dose of EFFENTORA®. If your doctor suspects EFFENTORA®-related increased sensitivity to pain (hyperalgesia), a reduction of your EFFENTORA® dose may be considered. For the most effective relief, let your doctor know about your pain and how EFFENTORA® is working for you, so that the dose can be changed if needed.

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. Use EFFENTORA® only as directed by your doctor.
2. EFFENTORA® is available in 100 mcg, 200 mcg, 400 mcg and 600 mcg and 800 mcg different dose strengths. Each strength has a different colour code as follows:

- 100 mcg – Blue
- 200 mcg – Orange
- 400 mcg – Green
- 600 mcg – Pink
- 800 mcg – Yellow

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®

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 do I dispose of EFFENTORA®?

Do not dispose of or throw away any medicines *via* wastewater or in household waste. Ask your pharmacist how to throw away medicines you no longer use.

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

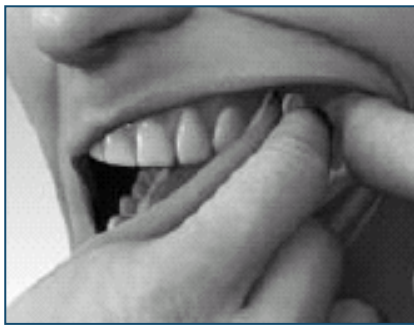
Figure 1



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

EFFENTORA®: RISKS OF USE

The following statement is on the outer of the UK EFFENTORA® packaging:

This product must only be used by patients already receiving maintenance opioid therapy for chronic cancer pain.

Accidental use can cause serious harm and be fatal.

*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.

What are some of the possible side effects of EFFENTORA®?

A full list of possible side effects is included in the Package Leaflet, which can be found within the EFFENTORA® box. Some possible side effects include:

Very common side effects (may affect more than 1 in 10 people)

- dizziness, headache
- feeling nauseous, vomiting
- at the site of tablet application: pain, ulcer, irritation, bleeding, numbness, loss of sensation, redness, swelling or spots

Common side effects (may affect up to 1 in 10 people)

- feeling anxious or confused, depression, insomnia
- abnormal taste, weight decreased
- sleepiness, sedation, excessive tiredness, weakness, migraine, numbness, swelling of arms or legs, drug withdrawal syndrome (may manifest with nausea, vomiting, diarrhoea, anxiety, chills, tremor, and sweating), shaking, falls, chills
- constipation, inflammation of the mouth, dry mouth, diarrhoea, heartburn, loss of appetite, stomach pain, uncomfortable stomach, indigestion, toothache, oral thrush
- itching, excessive sweating, rash
- shortness of breath, painful throat
- decrease in white cells in the blood, decrease in red blood cells, decreased or raised blood pressure, unusually fast heart rate
- muscle pain, back pain
- fatigue

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.

If you use more EFFENTORA® than you should:

- If you feel sleepy, sick or dizzy (common side effects) before the tablet is completely dissolved, rinse your mouth out with water and spit the remaining pieces of the tablet into a sink or toilet right away.
- Slow and/or shallow breathing (serious side effect) can occur if your dose is too high or you take too much EFFENTORA®, which can also lead to coma in severe cases.

If you become very sleepy or have slow and/or shallow breathing, you or your carer should immediately call for emergency help by calling 111 or 999 and then call your doctor.

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 life⁴

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 an electronic version of this guide and other helpful materials, see, the Electronic Medicines Compendium Risk Minimisation Materials Directory at: <https://www.medicines.org.uk/emc/rmm-directory> (enter 'EFFENTORA'® in 'Risk Minimisation Materials Search Area' and click search icon).



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.

References

1. Caraceni A, Shkodra M. Cancer pain assessment and classification. *Cancers*. 2019; 11: 510. doi:10.3390/cancers11040510 <https://www.mdpi.com/2072-6694/11/4/510/pdf?version=1554900943> [Accessed on 24 March 2023].
2. Fallon M, Giusti R, Aielli F, *et al.* On behalf of the ESMO Guidelines Committee. Management of cancer pain in adult patients: ESMO clinical practice guidelines. *Ann Oncol*. 2018; 29 (Suppl 4): iv166–iv191. <https://www.sciencedirect.com/science/article/pii/S0923753419316989/pdf?md5=5f77ca3f2346237b6544aff1f865f16a&pid=1-s2.0-S0923753419316989-main.pdf> [Accessed on 24 March 2023].
3. EFFENTORA® Product Information.
4. Centers for Disease Control and Prevention (CDC). Module 5: Assessing and addressing opioid use disorder (OUD) <https://www.cdc.gov/drugoverdose/training/oud/accessible/index.html> [Accessed on 24 March 2023].

DOSE MONITORING CARD

	Date	Time	Strength of EFFENTORA® tablet	Number of tablets
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2				
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