



About Effentora®
Information for
Patients and Carers

 **EFFENTORA**
fentanyl buccal tablet

You have been prescribed Effentora® (fentanyl buccal tablet) for breakthrough cancer pain (BTcP)

Important

- Do not use Effentora® unless you have been regularly using other opioid medicines for your persistent cancer pain for at least a week
- Do not give Effentora® to anyone else
- Keep Effentora® in a safe and secure place away from other people, especially children. Accidental use by an adult or a child is a medical emergency and may result in death. If an adult or child accidentally takes Effentora®, call for emergency medical help immediately
- Effentora® should only be used for BTcP
- Do not use Effentora® if you are below 18 years of age

Please read the Patient Information Leaflet that comes with Effentora® before you start taking it, and each time you get a new prescription, as it may contain new information. Please share this important information with members of your household. If you have any concerns about Effentora®, any other treatment you are having, or your medical condition, you should discuss these with your doctor.

The most important information you should know about Effentora® is:

1. Your doctor has prescribed a starting dose of Effentora®. Do not substitute Effentora® for other fentanyl medicines for BTcP without talking with your doctor
2. Effentora® can cause life-threatening effects, especially breathing problems:
 - If you are not regularly using other opioid medicines for your persistent cancer pain
 - If you do not use it **exactly** as prescribed by your doctor
3. Do not hesitate to talk with your doctor if you have any questions about your treatment

Before starting your treatment with Effentora®, be aware:

- **Use Effentora® only if taking a prescribed opioid pain medicine every day on a regular schedule, for at least a week, to control your persistent pain**
- You should never stop taking your opioid persistent pain treatment while taking Effentora® without first talking to your doctor
- Effentora® should **never** be used for **any pain other than your BTcP**

For complete information about Effentora®, please read the Patient Information Leaflet that came with your medicine

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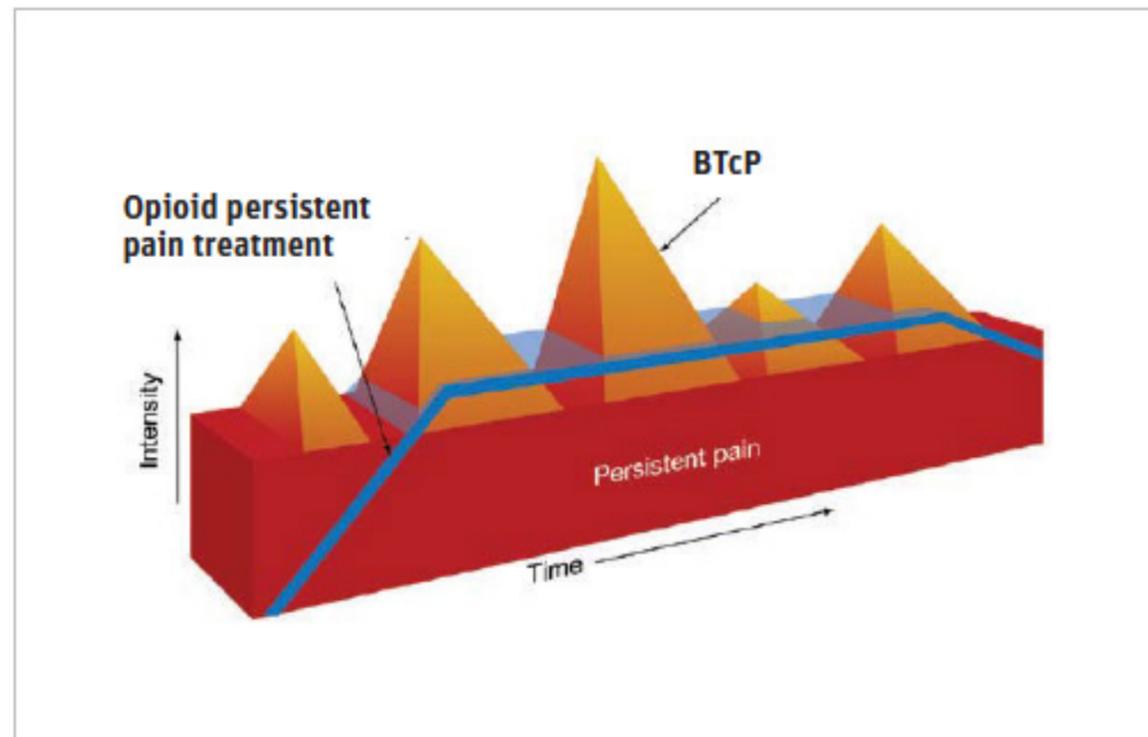
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Breakthrough cancer pain (BTcP)

What is BTcP?

Persistent cancer pain is pain related to your cancer that lasts throughout the day. Your doctor has given you an opioid medicine that should relieve this pain for the entire day.

Even if your opioid medicine controls your persistent cancer pain most of the time, you can still experience sudden flares or spikes of moderate to severe pain. This is **BTcP** – pain that ‘breaks through’ the pain relief provided by your opioid medicine.



Effentora®

What is Effentora®?

Effentora® is a pain-relieving medicine, belonging to a class of drugs called opioids, which is used to treat BTcP in adult patients with cancer who are already taking other pain treatment for their persistent cancer pain. Effentora® is a prescription medicine that contains the medicine fentanyl.

How does Effentora® work?

Effentora® buccal tablets need to be placed between the cheek and the gum, where they dissolve and the medicine, fentanyl, is absorbed through the lining of your mouth into the blood system. Taking the medicine this way allows it to be absorbed quickly to relieve your BTcP. As an alternative, Effentora® can be placed under the tongue. As soon as fentanyl enters the bloodstream, it is carried throughout your body. It travels to your central nervous system – the brain and spinal cord – where it works to relieve your pain.

How is Effentora® different from the medicine I already take for my persistent pain?

The medicine you already take for your persistent pain is an opioid medicine that works all day long. Effentora® is a treatment specifically for your BTcP (an additional, sudden pain episode that rises above the persistent pain). You must continue to take your opioid treatment for persistent pain while you are using Effentora®.

When should I use Effentora®?

Once your doctor has determined that Effentora® is an appropriate treatment for you, you should take Effentora® as soon as you start to feel an episode of BTcP. You should only use Effentora® if you are using other opioid pain medicine on a daily basis.

Does Effentora® have a taste?

Effentora® contains no added flavours. You may sense a slight taste, or you may notice nothing at all.

Is there sugar in Effentora®?

No. Effentora® is sugar-free.

How is Effentora® packaged?

Effentora® comes in individually sealed, child-resistant blister packs.

Remember

You must continue to take your opioid medicine for persistent pain while you are using Effentora®

- Only use Effentora® if you are using other opioid pain medicine on a daily basis
- Only use Effentora® if you have been experiencing BTcP episodes
- Never stop using your opioid treatment for persistent pain while you are taking Effentora® without talking to your doctor
- Never use Effentora® for the treatment of any pain other than BTcP
- Under no circumstance should you give Effentora® to anyone else
- Use Effentora® exactly as your doctor has told you

Using Effentora®

How do I take Effentora®?



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. **Do not** attempt to push the tablet through the blister because this can damage the tablet



2. Place it

- Remove the tablet from the blister unit and **immediately** place the entire tablet between the cheek and gum, near an upper or lower molar. Do not attempt to crush or split the tablet
- Alternatively, if preferred, the tablet may be placed under the tongue
- Do not bite, suck, chew, or swallow the tablet, as this will result in less pain relief than when taken as directed

How do I take Effentora®?



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

Remember

Use Effentora® exactly as prescribed by your doctor

- It is important that you understand the correct way to use Effentora®. Read the instructions in the Patient Information Leaflet and this brochure, and ask your doctor or pharmacist if there is anything further you want to know
- Keep tablets in their blister packages until you are ready to take Effentora® in order to protect them from moisture. Do not store Effentora® in pill boxes. Once a blister is opened, the tablet must be taken immediately

How does my doctor find the dose of Effentora® that is right for me?

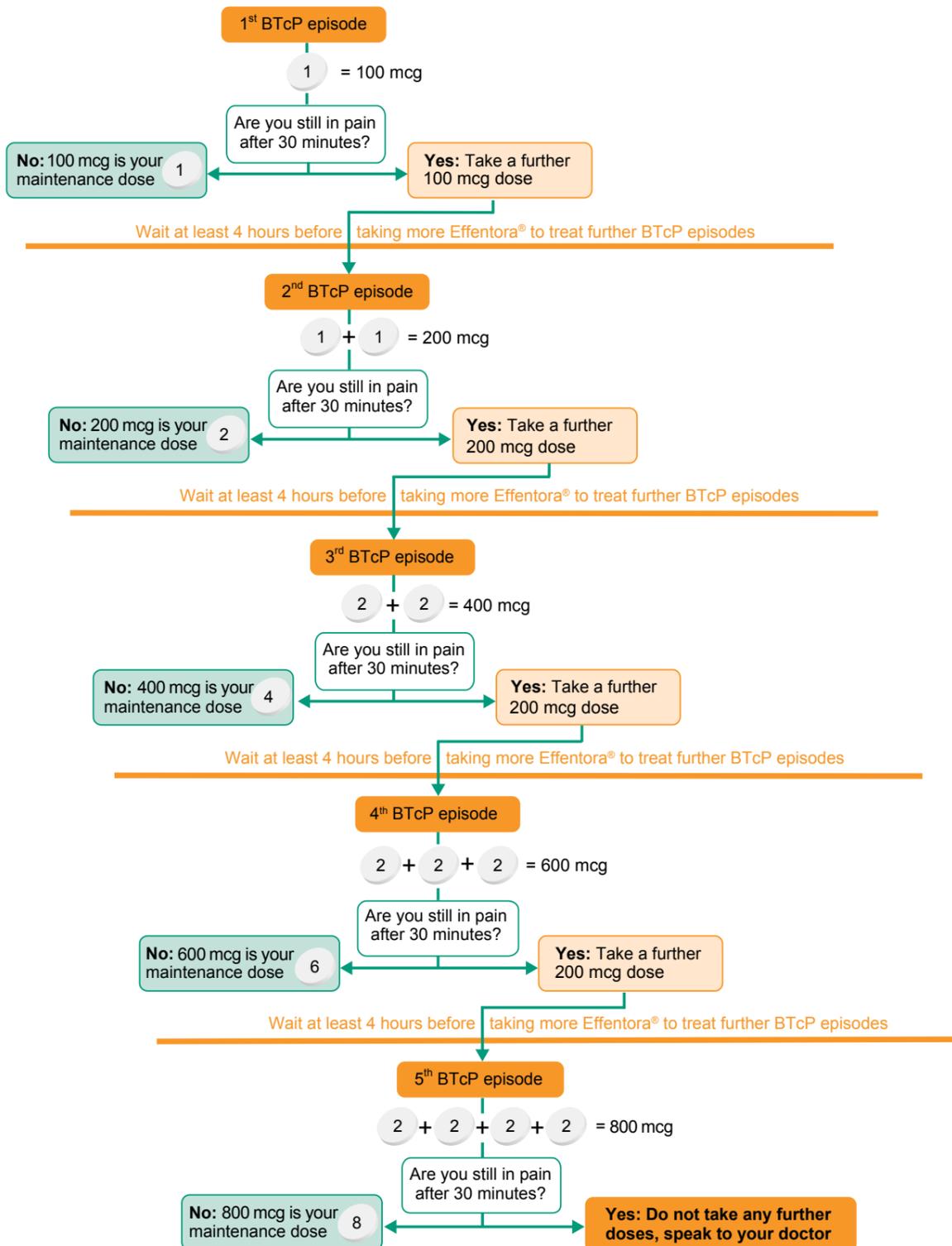
Effentora® comes in several dosage strengths.

Your doctor may gradually increase the dosage strength of Effentora® to find the right dose for you. During this process, your doctor may instruct you to take more than one tablet at the same time.

The titration process

- When you first start taking Effentora®, your doctor will work with you to find the dose that will effectively relieve your BTcP with minimal undesirable effects - this dose is known as the maintenance dose
- The process of finding the right maintenance dose is called the titration process
- During the titration process you may be asked to take more than one tablet at a time; when doing this you should place tablets at each side of the mouth
- Once your maintenance dose has been determined, you will take one tablet of that strength rather than using multiple tablets

The titration process



My Effentora® maintenance dose is:

Remember

When you and your doctor are in the process of finding the right dose of Effentora® to relieve your BTcP:



Your doctor may instruct you to use more than one tablet of the same strength at the same time (up to maximum of 4 tablets)

By following your doctor's instructions during this dose adjustment period and telling the doctor how you are feeling, you can help to determine the correct dose for you. A Treatment Diary can be useful to help you to remember your experiences, so that you can discuss them with your doctor. Ask your doctor for details.

Once you are on a regular dose of Effentora®, your doctor will prescribe tablets containing that dose.

You should then use only one Effentora® tablet per BTcP episode.

What if I still have pain after a single dose of Effentora® once my correct dose has been determined?

Contact your doctor if your correct dose of Effentora® does not relieve your BTcP. Your doctor will decide if your dose needs to be changed.

When can I treat another BTcP episode with Effentora®?

Follow the instructions that you received from your doctor or pharmacist about how often to take Effentora®.

Wait at least 4 hours before treating another episode. If you regularly suffer more than 4 BTcP episodes *per* day, you should contact your doctor.

Can I bite, chew, suck or swallow Effentora®?

No. Do not bite, chew or suck an Effentora® tablet, or swallow it whole.

What happens if I swallow Effentora®?

If you swallow Effentora® before it can cross the lining of your mouth, you may get less relief for your BTcP.

Can I take Effentora® if I have a dry mouth?

Yes. You may drink some water to moisten your mouth before taking Effentora®.

While taking Effentora®, should I continue taking my opioid treatment for persistent pain?

You **must** take your opioid medicine for persistent cancer pain as long as you are taking Effentora®. Do not stop taking your opioid treatment for persistent pain without talking to your doctor.

Remember

Use Effentora® exactly as prescribed by your doctor

- Wait at least 30 minutes before taking one more dose of Effentora® for an unrelieved BTcP episode during the dose adjustment phase
- Wait at least 4 hours before treating another BTcP episode
- If you regularly suffer from more than 4 BTcP episodes per day, you should contact your doctor

Possible side effects of Effentora®

What are the possible or likely side effects of Effentora®?

The most serious side effects are shallow breathing, low blood pressure and shock. Effentora like other fentanyl products can cause very severe breathing problems which can lead to death. If you become very sleepy or have slow and/or shallow breathing, you or your carer should call immediately for emergency medical help.

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 by the occurrence of the following side effects: 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

Tolerance, dependence, and addiction

Opiates and narcotics are powerful painkillers that cause drowsiness and sometimes feelings of happiness and euphoria.

Drug abuse can lead to drug dependence or addiction. People who use drugs for pain relief may become dependent, although this is rare in those who do not have a history of addiction.

It is important to understand the meaning of the terms tolerance, dependence, and addiction when discussing substance abuse and the use of prescription medications such as opioid painkillers.

The most important distinction between these concepts is that tolerance and dependence refer to the physical consequences of drug use. In contrast, addiction is a descriptive term that refers to a need to engage in harmful behaviour such as drug use.

Drugs that result in the development of tolerance and physical dependence often have the potential to cause addiction, but not always.

For the last few years, scientist and physicians use the term of Substance Use Disorders (SUD), which is the persistent use of drugs despite substantial harm and adverse consequences. SUD are characterised by an array of mental/emotional, physical, and behavioural problems such as chronic guilt; an inability to reduce or stop consuming the substance(s) despite repeated attempts; driving while intoxicated; and physiological withdrawal symptoms.

For further information on Effentora® and possible side effects, see the Patient Information Leaflet that comes with your medicine. If you notice any side effects when taking Effentora®, contact your doctor.

Possible side effects of Effentora®

What should I do if I have any of the following symptoms?

Call your doctor and get emergency medical help right away if you:

- Have trouble breathing
- Have slow, shallow breathing (little chest movement while breathing)
- Have extreme drowsiness, with slowed breathing
- Feel faint, very dizzy, confused, or have unusual symptoms

These symptoms may indicate that you have taken too much Effentora® (an overdose), or that the dose you are taking is too high for you. If you feel very dizzy or very sleepy before the tablet has completely dissolved, you should immediately rinse your mouth with water and spit the remaining pieces of the tablet into a sink or toilet right away.

In addition, contact your doctor immediately if you experience a combination of the following symptoms

- Nausea, vomiting, anorexia, fatigue, weakness, dizziness and low blood pressure

Together these symptoms may be a sign of a potentially life-threatening condition called adrenal insufficiency (a condition in which the adrenal glands do not produce enough hormones).

These symptoms may lead to serious problems or death if not treated right away

Remember

Know when to call for emergency medical help

The most serious side effects of Effentora® are shallow breathing, low blood pressure and shock. If you have trouble breathing, have slow, shallow breathing, extreme drowsiness with slowed breathing, feel faint, very dizzy, confused or have unusual symptoms:

- Immediately spit out the remains of the tablet
- Do not take another dose of Effentora®
- Call your doctor and get emergency medical help right away

Interactions with Effentora®

Can I take or use other medicines while taking Effentora®?

Before starting Effentora®, please tell your doctor or pharmacist if you are taking, or might take, or have recently taken any of the following medicines:

- Concomitant use of Effentora and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible. However if your doctor does prescribe Effentora together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor
- Some muscle relaxants - such as baclofen, diazepam
- Please tell you doctor about all sedative medicines you are taking (such as sleeping pills, medicines to treat anxiety, some medicines to treat allergic reactions [antihistamines]), or tranquillisers and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms
- Any medicines that might have an effect on the way in which your body breaks down Effentora®, such as ritonavir, nelfinavir, amprenavir, and fosamprenavir (medicines that help control HIV infection) or other so-called CYP3A4 inhibitors, such as ketoconazole, itraconazole, and fluconazole (used for treatment of fungal infections), troleandomycin, clarithromycin or erythromycin (medicines for treatment of bacterial infections), aprepitant (used for severe nausea), and diltiazem and verapamil (medicines for treatment of high blood pressure or heart disease)

- Medicines called monoamine-oxidase (MAO) inhibitors (used for severe depression), or have done so in the past 2 weeks
- Certain types of strong pain killers, called partial agonist/antagonists e.g. buprenorphine, nalbuphine and pentazocine (medicines for treatment of pain). You could experience symptoms of withdrawal syndrome (nausea, vomiting, diarrhoea, anxiety, chills, tremor, and sweating) while using these medicines
- The risk of side effects increases if you are taking medicines such as certain antidepressants or antipsychotics. Effentora may interact with these medicines and you may experience mental status changes (e.g. agitation, hallucinations, coma), and other effects such as body temperature above 38°C, increase in heart rate, unstable blood pressure, and exaggeration of reflexes, muscular rigidity, lack of coordination and/or gastrointestinal symptoms (e.g. nausea, vomiting, diarrhoea). Your doctor will tell you whether Effentora is suitable for you

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, vitamins or herbal supplements.

Can I take Effentora® with food or drink?

Effentora® may be used before or after, but not during, meals. You may drink some water before using Effentora® to help moisten your mouth, but you should not drink or eat anything while taking the medicine.

- You should not drink grapefruit juice while using Effentora® because it may affect the way your body breaks down Effentora®
- Do not drink alcohol while using Effentora® as this can increase the risk of experiencing dangerous side effects including death

Safe use, storage and disposal of Effentora®

What do I need to know before I start taking Effentora®?

You should not use Effentora® if:

- You have not been using a prescribed opioid medicine (e.g codeine, fentanyl, hydromorphone, morphine, oxycodone, pethidine), every day on a regular schedule, for at least a week, to control your persistent pain. If you have not been using these medicines you must **not use** Effentora®, because it may increase the risk of your breathing becoming dangerously slow and/or shallow, or even stopping
- You are allergic to fentanyl or any of the other ingredients of Effentora®
- You suffer from severe breathing problems or severe obstructive lung conditions
- If you suffer from short-term pain other than breakthrough pain

You should take special care with Effentora® if you have any of the following and should talk to your doctor or pharmacist before starting Effentora®:

- Your other opioid medicine taken for your persistent (around-the-clock) cancer pain is not stabilised yet
- You are suffering from any condition that has an effect on your breathing (such as asthma, wheezing, or shortness of breath)
- You have a head injury
- You have liver or kidney problems, as these organs have an effect on the way in which your system breaks down the medicine
- You have low amount of fluid in the circulation or low blood pressure

- You are over 65 years old - you may need a lower dose and any dose increase will be reviewed very carefully by your doctor
- You have problems with your heart especially slow heart rate
- You use benzodiazepines. Using benzodiazepines can increase the chances of getting serious side effects including death
- You use antidepressants or antipsychotics, (selective serotonin reuptake inhibitors [SSRIs], serotonin norepinephrine reuptake inhibitors [SNRIs], monoamine oxidase (MAO) inhibitors. The use of these medicines with Effentora® can lead to a serotonin syndrome, a potentially life-threatening condition
- You have ever developed adrenal insufficiency, a condition in which the adrenal glands do not produce enough hormones or lack of sex hormones (androgen deficiency) with opioid use
- You have ever abused or been dependent on opioids or any other drug, alcohol or illegal drugs
- You drink alcohol; please refer to section Effentora® with food or drink

Can I drive or operate machinery after taking Effentora®?

You should discuss with your doctor whether it is safe for you to drive or operate machinery after taking Effentora®. Do not drive or operate machinery if you are feeling sleepy or dizzy, have blurred or double vision, or have difficulty in concentrating. It is important that you know how you react to Effentora® before driving or operating machinery.

Safe use, storage and disposal of Effentora®

What should I do if someone else accidentally takes Effentora®?

If you think someone has accidentally taken Effentora®, please seek immediate medical assistance. Try to keep the person awake until emergency help arrives.

If someone has accidentally taken Effentora®, they may have the same side effects as described in the question “What if I take more Effentora® than I should?”

What if I take more Effentora® than I should?

The most common side effects of taking too much Effentora® are feeling sleepy, sick or dizzy. If you begin to feel very dizzy or very sleepy before the tablet is completely dissolved, rinse your mouth with water and spit the remaining pieces of the tablet into a sink or toilet right away.

A serious side effect of Effentora® is slow and/or shallow breathing. This can occur if your dose of Effentora® is too high or if you take too much Effentora®. If this occurs, please seek immediate medical assistance.

What if I forget to take Effentora®?

If the BTcP is still ongoing, you may take Effentora® as prescribed by your doctor. If the BTcP has stopped, do not take Effentora® until the next BTcP episode.

Preventing painkiller abuse in cancer patients

Your prescribing physician or nurse will maintain an active dialogue with you throughout the duration of your opioid painkiller treatment. This is important to ensure your use of the opioid painkiller treatment is only as prescribed, do not increase the dose or take extra dose without talking to your physician, nurse or pharmacist. Talk to them as they can recognise if you exhibit any behaviours, which point to drug misuse or abuse.

Prevalence of dependence and addiction

The best current evidence of addiction risk in patients treated for chronic pain in both hospital and community settings, estimates that 8-12% of long term opioid users meet the criteria for a current or past opioid use disorder.

In September 2020, the MHRA published a guidance for patients titled: ‘Opioid medicines and the risk of addiction’. The guidance is available at: <https://www.gov.uk/guidance/opioid-medicines-and-the-risk-of-addiction>

How should I store Effentora®?

Store Effentora® in the original package in order to protect from moisture.

The pain-relieving medicine in Effentora® is very strong and could be life-threatening if taken accidentally by a child. Effentora® must be kept in a safe place out of the sight and reach of children.

Do not use Effentora® after the expiry/use before date shown on the blister package label and the carton. The expiry date refers to the last day of that month.

Safe use, storage and disposal of Effentora®

What if I no longer need to take Effentora®?

You should discontinue Effentora® when it is no longer required. You should continue to take your usual opioid medicine to treat your persistent pain and you may contact your doctor to confirm its correct dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

How should I dispose of unopened Effentora® tablets when they are no longer needed?

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Remember

Prevent theft and misuse of Effentora®

- Keep Effentora® in a safe place, whilst in and outside your home, to protect it from being stolen. It can be a target for people who abuse medicines
- Never give Effentora® to anyone else, even if they have the same symptoms as you, as it may cause serious or life-threatening side-effects, including death
- If you think someone has accidentally taken Effentora®, get emergency medical help immediately and try to keep the person awake until help arrives
- Keep Effentora® out of the sight and reach of children
- Medicines should not be disposed of *via* wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment

Important considerations

Continue to use your persistent pain treatment every day while you are using Effentora®

Effentora® must only be used if you are regularly using other opioid pain medicines and your body is used to these medicines.

Use Effentora® exactly as prescribed by your doctor

It is important to understand the correct way to use Effentora®. Wait at least 4 hours before treating another episode of BTcP and talk to your doctor if you regularly need to treat more than 4 episodes per day.

Keep Effentora® out of the sight and reach of children

Keep Effentora® in a safe and secure place away from children and anyone for whom it has not been prescribed.

Prevent theft and misuse of Effentora®

Keep Effentora® in a safe place to protect it from being stolen. It can be a target for people who abuse medicines.

If someone accidentally takes Effentora®

Call for emergency help immediately

See the Patient Information Leaflet that comes in the Effentora® package for additional important information. If you have questions after reading it, speak with your doctor

Additional information

Doctor:

Day time phone number:

Out of hours office phone number:

Emergency medical care phone number:

Other healthcare team members

Name:

Phone:

Name:

Phone:

Name:

Phone:

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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: www.mhra.gov.uk/yellowcard.

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

Further information

For further information regarding your treatment and prescription with Effentora®, please contact your doctor.

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