

B. PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Effentora 100 micrograms buccal tablets

Effentora 200 micrograms buccal tablets

Effentora 400 micrograms buccal tablets

Effentora 600 micrograms buccal tablets

Effentora 800 micrograms buccal tablets

Fentanyl

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Effentora is and what it is used for
2. Before you use Effentora
3. How to use Effentora
4. Possible side effects
5. How to store Effentora
6. Further information

1. WHAT EFFENTORA IS AND WHAT IT IS USED FOR

Effentora is a pain-relieving medicine known as an opioid, which is used to treat breakthrough pain in adult patients with cancer who are already taking other opioid pain medicines for their constant (around-the-clock) cancer pain.

Breakthrough pain is additional, sudden pain that occurs in spite of you having taken your usual opioid pain-relieving medicines.

2. BEFORE YOU USE EFFENTORA

Do not use Effentora if:

- You have not been using a prescribed opioid pain medicine 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 that breathing could become dangerously slow and/or shallow, or even stop.
- You are allergic (hypersensitive) to fentanyl or any of the other ingredients of Effentora.
- You suffer from severe breathing problems or severe obstructive lung conditions.

Take special care with Effentora

If you have any of the following, talk to your doctor or pharmacist before starting Effentora:

- Your other opioid pain medicine taken for your constant (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 an exceptionally slow heart rate or other heart problems.
- 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

Taking/using other medicines

Please tell your doctor or pharmacist before starting Effentora if you are taking or have recently taken any of the following medicines:

- Any medicines which might normally make you sleepy (have a sedative effect) such as sleeping pills, medicines to treat anxiety, antihistamines, or tranquillisers.
- 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, or fluconazole (used for treatment of fungal infections), troleandomycine, 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 diseases).
- Medicines called monoamine-oxidase (MAO) inhibitors (used for severe depression) or have done so in the past 2 weeks.

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

Using 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. It can increase the risk of experiencing dangerous side effects.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Effentora should not be used during pregnancy unless you have discussed this with your doctor. You should not use Effentora during childbirth because fentanyl may cause respiratory depression in the new-born child.

Fentanyl can get into breast milk and may cause side effects in the breast-fed infant. Do not use Effentora if you are breast-feeding unless you have discussed this with your doctor.

Driving and using machines

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 you know how you react to Effentora before driving or operating machinery.

Important information about some of the ingredients of Effentora

Each tablet of Effentora 100 micrograms contains 8 mg of sodium. Each tablet of Effentora 200 micrograms, Effentora 400 micrograms, Effentora 600 micrograms and Effentora 800 micrograms contains 16 mg of sodium. You should take this into consideration if you are on a controlled sodium diet and seek advice from your doctor.

3. HOW TO USE EFFENTORA

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.

Dosage and frequency

When you first start using Effentora, your doctor will work with you to find the dose that will relieve your breakthrough pain. It is very important that you use Effentora exactly as the doctor tells you. The initial dose is 100 micrograms. During determination of your right dose, your doctor may instruct you to take more than one tablet per episode.

Once the right dose has been determined with your doctor, use 1 tablet for an episode of breakthrough pain. If your breakthrough pain is not relieved after 30 minutes, use only 1 more tablet of Effentora at this time.

Contact your doctor if your right dose of Effentora does not relieve your breakthrough pain. Your doctor will decide if your dose needs to be changed.

Wait at least 4 hours before treating another episode of breakthrough pain with Effentora.

You must let your doctor know immediately if you are using Effentora more than four times per day, as he may change your medicine for your persistent pain. When your persistent pain is controlled again, your doctor may need to change your dose of Effentora. 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 taking this medicine, you should contact your doctor.

Taking the medicine

- 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.



- Remove the tablet from the blister unit and **immediately** place the entire tablet above a rear molar tooth between the upper gum and the cheek (as shown in the picture). Do not attempt to crush or split the tablet.



- Do not bite, suck, chew, or swallow the tablet, as this will result in less pain relief than when taken as directed.
- 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.
- After 30 minutes, if pieces of the tablet remain, they may be swallowed with a glass of water.

If you use more Effentora than you should

- The most common side effects 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 to do if someone 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 section “If you use more Effentora than you should”.

If you forget to use Effentora

If the breakthrough pain is still ongoing, you may take Effentora as prescribed by your physician. If the breakthrough pain has stopped, do not take Effentora until the next breakthrough pain episode.

If you stop using Effentora

You should discontinue Effentora when 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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Effentora can have side effects, although not everybody gets them. If you notice any of these, contact your doctor.

The most serious side effects are shallow breathing, low blood pressure and shock. If you become very sleepy or have slow and/or shallow breathing, you or your carer should contact your doctor immediately and call for emergency help.

Very common side effects (affects more than 1 user in 10):

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

Common side effects (affects 1 to 10 users in 100):

- disorientation, feeling elated
- abnormal taste
- sleepiness, sedation, excessive tiredness, headache, shaking
- vomiting, constipation, inflammation of the mouth, dry mouth, diarrhoea
- itching, excessive sweating

Uncommon side effects (affects 1 to 10 users in 1,000):

- sore or painful throat, collection of pus under the skin in the mouth
- abnormal white cells in the blood, decrease in white cells in the blood, decrease in cells that help the blood to clot, decrease in red blood cells

- feeling: anxious, nervous, confused, abnormal, jittery or slow; seeing or hearing things that aren't really there, inability to sleep, reduced consciousness, lack of concentration, disturbance in thinking, numbness, loss of balance, migraine, movements disturbance, vertigo, problem with speaking, ringing in the ear, ear discomfort
- disturbed or blurred vision, red eye, abnormal sensation in eye, observing flashes of light
- unusually fast or low heart rate, hot flushes, raised blood pressure
- shortness of breath
- one or more of the following problems in the mouth: ulcer, loss of sensation, discomfort, blisters, unusual colour, soft tissue disorder, tongue disorder, painful or blistered or ulcerated tongue, gum pain, chapped or dry lips, oral thrush, tooth disorder, toothache
- heartburn, loss of appetite, uncomfortable stomach, indigestion, stomach pain, inflammation of the oesophagus
- cold sweat, swollen face, rash, generalised itching, hair loss, brittle nails, muscle pain, muscle twitching, muscular weakness, back pain, weakness, feeling unwell, chest discomfort, thirst, chills, feeling cold, feeling hot, falls, difficulty passing water
- drug withdrawal syndrome

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE EFFENTORA

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

- Do not use Effentora after the expiry/use before date shown on the blister package label and the carton.
- Store in the original package in order to protect from moisture.
- 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.

6. FURTHER INFORMATION

What Effentora contains

The active substance is fentanyl. Each tablet contains either:

- 100 micrograms fentanyl (as citrate)
- 200 micrograms fentanyl (as citrate)
- 400 micrograms fentanyl (as citrate)
- 600 micrograms fentanyl (as citrate)
- 800 micrograms fentanyl (as citrate)

The other ingredients are mannitol, sodium starch glycolate type A, sodium hydrogen carbonate, sodium carbonate anhydrous, citric acid anhydrous, magnesium stearate.

What Effentora looks like and contents of the pack

The buccal tablets are flat-faced, round bevelled-edge tablet, embossed one side with a "C" and on the other side with "1" for Effentora 100 micrograms, with "2" for Effentora 200 micrograms, with "4" for Effentora 400 micrograms, with "6" for Effentora 600 micrograms, with "8" for Effentora 800 micrograms.

Each blister contains 4 buccal tablets, supplied in cartons of 4 or 28 buccal tablets. Not all pack sizes may be marketed.

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Detailed information on this medicine is available on the European Medicines Agency (EMA) web site: <http://www.emea.europa.eu>