

EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)**EFFENTORA****EPAR summary for the public**

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.

If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Effentora?

Effentora is a medicine containing the active substance fentanyl. It is available as buccal tablets (tablets that dissolve in the mouth), containing 100, 200, 400, 600 or 800 micrograms of fentanyl.

What is Effentora used for?

Effentora is used to treat 'breakthrough' pain in adults with cancer who are already using opioids (a group of painkillers that includes morphine and fentanyl) to control long-term cancer pain.

'Breakthrough pain' is when a patient experiences additional, sudden pain in spite of ongoing treatment with painkillers.

The medicine can only be obtained with a prescription.

How is Effentora used?

Treatment with Effentora should be initiated and remain under the guidance of a doctor who has experience in the management of opioid treatment in cancer patients.

Effentora is taken at the start of a breakthrough pain episode. The tablets should be removed from the packaging immediately before being placed between the gum and the cheek at the back of the mouth.

The tablet usually dissolves in 14 to 25 minutes, releasing the active substance, which is absorbed directly into the bloodstream. After 30 minutes, any pieces of the tablet remaining can be swallowed with a glass of water. The tablets should not be broken or crushed, and they should not be sucked, chewed or swallowed whole. Patients should not eat or drink anything while the tablet is in the mouth.

When a patient starts to take Effentora, the doctor will need to work out the appropriate individual dose that will provide adequate pain relief for the patient with few side effects. The usual starting dose is one 100 microgram tablet, but this can be increased until the appropriate maintenance dose is found. The patient should be monitored carefully while the dose is increased.

The final individual dose must include no more than two tablets, but it can be adjusted if a patient consistently has more than four episodes of breakthrough pain per day. Doses above 800 micrograms have not been tested. There must be a gap of at least four hours between treating each episode of pain. See the Package Leaflet for further information.

How does Effentora work?

The active substance in Effentora, fentanyl, is an opioid (a strong painkiller that is related to morphine). It is a well-known substance, which has been used to control pain for many years. In

Effentora, fentanyl is given as a buccal tablet, so that the fentanyl is absorbed through the lining of the mouth. Once in the bloodstream, fentanyl acts on receptors in the brain and spinal cord to prevent pain.

How has Effentora been studied?

Because fentanyl has been in use for many years, the company presented data from the scientific literature, as well as from studies that it had carried out.

The effectiveness of Effentora in treating breakthrough pain was tested in two main studies involving a total of 150 adults with cancer who were being treated with opioids. The first study included 72 patients and the second included 78. In both studies, each patient was treated during 10 separate episodes of breakthrough pain: in seven of these episodes, each patient received Effentora, and in the other three episodes, each patient received placebo (a dummy tablet). The main measure of effectiveness was the change in pain intensity over the first 30 or 60 minutes after taking the tablet. Each patient ranked their pain intensity on an 11-point scale.

What benefit has Effentora shown during the studies?

Effentora was more effective than placebo in reducing pain in both studies. In the first study, pain intensity had fallen by an average of 3.2 points at 30 minutes after the patients took Effentora and by 2.0 points after they took placebo. In the second study, pain intensity had fallen by 9.7 points at 60 minutes after Effentora and by 4.9 points after placebo.

What is the risk associated with Effentora?

The most common side effects with Effentora (seen in more than 1 patient in 10) are dizziness, nausea (feeling sick) and reactions at the site of application including pain, ulcers, irritation, unusual sensations, numbness, redness, swelling and spots. Effentora can also cause the side effects typically seen with other opioids, but these tend to decrease or stop with continued use. The most serious of these are respiratory depression (slow or shallow breathing), circulatory depression (slow heart beat), hypotension (low blood pressure) and shock (insufficient blood flow to the tissues). Patients should be closely monitored for these side effects. For the full list of all side effects reported with Effentora, see the Package Leaflet.

Effentora should not be used in people who may be hypersensitive (allergic) to fentanyl or any of the other ingredients. It should also not be used in patients who are not already taking opioids to maintain pain control, who have severe respiratory depression, or who have a severe disease involving obstruction of the lungs.

Effentora should be used with caution in patients who have moderate or severe problems with their liver or kidneys.

Why has Effentora been approved?

The Committee for Medicinal Products for Human Use (CHMP) decided that Effentora's benefits are greater than its risks for the treatment of breakthrough pain in adults with cancer who are already receiving maintenance opioid therapy for chronic cancer pain. The Committee recommended that Effentora be given marketing authorisation.

Which measures are being taken to ensure the safe use of Effentora?

The company that makes Effentora will provide educational materials to make sure that healthcare workers are aware of the fact that the medicine could be abused. The company will also remind healthcare workers about how the medicine should be used safely and the risks of accidental exposure to fentanyl.

Other information about Effentora:

The European Commission granted a marketing authorisation valid throughout the European Union for Effentora to Cephalon Europe on 4 April 2008.

The full EPAR for Effentora can be found [here](#).

This summary was last updated in 04-2008.