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EPAR summary for the public

Effentora

fentanyl

This is a summary of the European public assessment report (EPAR) for Effentora. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Effentora.

What is Effentora?

Effentora is a medicine that contains the active substance fentanyl. It is available as 'buccal tablets' (tablets that dissolve in the mouth). The tablets contain 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.

This medicine can only be obtained by 'special' prescription. This means that because the medicine can be misused or cause addiction, it is used under stricter conditions than normal.

How is Effentora used?

Treatment with Effentora should be started by 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. Alternatively, the tablets can be placed under the tongue. The tablets usually dissolve in 14 to 25 minutes, releasing the active substance, which is absorbed directly into the bloodstream. After 30 minutes, any pieces of tablet remaining can be swallowed with a glass of water. The tablets should not be broken or crushed, and

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

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 patient should be monitored carefully while the dose is increased. Once the appropriate dose for the patient has been found, the patient should take this dose as a single tablet. If this dose stops controlling the pain well enough, the doctor will need to work out a new individual dose. Doses of Effentora above 800 micrograms have not been tested. There must be a gap of at least four hours between treating each episode of pain.

Patients should not possess or use any other medicines containing fentanyl for the treatment of breakthrough cancer pain at the same time as using Effentora. They should only have the necessary strengths of Effentora tablets available at any one time, to prevent confusion and possible overdose. See the package leaflet for further information.

How does Effentora work?

The active substance in Effentora, fentanyl, is an opioid. It is a well-known substance, which has been used to control pain for many years. In Effentora, it 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 ability of Effentora to treat breakthrough pain was tested in two main studies involving a total of 150 adults with cancer who were being treated with opioids. 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 (that may affect more than 1 patient in 10) are dizziness, headache, nausea (feeling sick), vomiting, and reactions at the site of application including bleeding, 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 (inhibition of breathing), circulatory depression (slow heartbeat), hypotension (low blood pressure) and shock (a steep fall in blood pressure). 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 must not be used in patients who are not already taking opioids to maintain pain control, who have severe respiratory depression, or who have severe obstructive lung conditions (diseases that severely impede breathing). It must not be used to treat short-term pain other than breakthrough pain. For the full list of restrictions, see the package leaflet.

Why has Effentora been approved?

The CHMP decided that Effentora's benefits are greater than its risks and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Effentora?

A risk management plan has been developed to ensure that Effentora is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Effentora, including the appropriate precautions to be followed by healthcare professionals and patients.

The company that makes Effentora will also provide educational materials in each European Union (EU) Member State to make sure that patients and doctors are aware of how the medicine should be used safely, the risks of accidental exposure to fentanyl and how to dispose of Effentora.

Other information about Effentora

The European Commission granted a marketing authorisation valid throughout the EU for Effentora on 4 April 2008.

The full EPAR for Effentora can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Effentora, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 03-2014.