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PecFent (*fentanyl*)

An overview of PecFent and why it is authorised in the EU

What is PecFent and what is it used for?

PecFent is a medicine used to treat breakthrough pain in adult patients with cancer. Breakthrough pain is when a patient experiences additional, sudden pain in spite of ongoing treatment with painkillers. PecFent is used in patients who are already using opioids (a group of painkillers that includes morphine and fentanyl) to control long-term cancer pain.

PecFent is a 'hybrid medicine'. This means that it is similar to 'reference medicines' containing the same active substance, but given in a different way. While the reference medicines Effentora (buccal tablets) and Actiq (lozenges) are taken by mouth, PecFent is given as a spray into the nose.

PecFent contains the active substance fentanyl.

How is PecFent used?

PecFent is available as a nasal spray (100 and 400 micrograms per spray) and 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. Treatment with PecFent should be started by and remain under the supervision of a doctor who has experience in managing opioid treatment in cancer patients. The doctor should keep in mind the potential for PecFent to be abused.

When a patient starts to take PecFent the doctor will need to work out the appropriate dose that will provide adequate pain relief with as few side effects as possible. The first trial dose should always be 100 micrograms (one spray into one nostril). The patient should be monitored carefully while the dose is increased.

The doses should be given as either one spray or two sprays of the same strength. Patients should not take more than four doses a day and should leave a gap of at least four hours between treating each episode of pain.

For more information about using PecFent, see the package leaflet or contact your doctor or pharmacist.

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How does PecFent work?

The active substance in PecFent, fentanyl, is an opioid. It is a well-known substance, which has been used to control pain for many years. When the patient sprays PecFent into the nose, a dose of fentanyl is rapidly absorbed into the blood stream through the blood vessels in the nose. Once in the bloodstream, fentanyl acts on receptors in the brain and spinal cord to relieve pain.

What benefits of PecFent have been shown in studies?

Because PecFent is a hybrid medicine, the applicant presented data on the reference medicines in addition to results from its own studies.

In one main study, PecFent was shown to be more effective than placebo (a dummy treatment) at treating breakthrough cancer pain in 83 adults who were being treated with opioids. The main measure of effectiveness was the change in the severity of pain measured by the patients ranking their pain on a scale from 0 to 10. The average reduction in pain during the first 30 minutes after use was 6.6 points in patients receiving PecFent compared with 4.5 in those receiving placebo.

An additional study measured the 'acceptability' of PecFent by the patients, rating how satisfied they were with PecFent, and how easy and convenient they found it to use. In this study, patients reported that they were 'satisfied' or 'very satisfied' with PecFent treatment for around 90% of breakthrough pain episodes.

What are the risks associated with PecFent?

Typical opioid side effects are to be expected with PecFent; often these will stop or become less intense with continued use of the medicine. The most serious of these side effects 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 side effects reported with PecFent, see the package leaflet.

PecFent must not be used in patients who are not already taking opioids to maintain pain control, who have severe respiratory depression (inhibition of breathing) 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 is PecFent authorised in the EU?

The European Medicines Agency noted that there was a need for fast-acting pain medicines for breakthrough pain in patients with cancer. Based on available data, the Agency concluded that PecFent's benefits are greater than its risks and it can be authorised for use in the EU.

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

The company that markets PecFent will provide educational materials in each EU Member State to make sure that patients, doctors and pharmacists are aware of how PecFent should be used, the risk of accidental exposure to fentanyl and how to dispose of the medicine.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of PecFent have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of PecFent are continuously monitored. Side effects reported with PecFent are carefully evaluated and any necessary action taken to protect patients.

Other information about PecFent:

PecFent received a marketing authorisation valid throughout the EU on 31 August 2010.

Further information on PecFent can be found on the Agency's website: EMA website/Find medicine/Human medicines/European Public Assessment Reports.

This overview was last updated in 06-2018.