



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Instanyl (*fentanyl*)

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

### What is Instanyl what is it used for?

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

Instanyl contains the active substance fentanyl.

### How is Instanyl used?

Instanyl is available as a nasal spray (50, 100 and 200 micrograms per dose). It is available in single-dose containers and in multidose containers.

The 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.

Treatment with Instanyl should be started by and remain under the supervision of a doctor who has experience in the management of opioid treatment in cancer patients. The doctor should keep in mind the potential for Instanyl to be abused.

Before starting treatment with Instanyl, the patient's long-term pain should be well controlled by opioid pain killers and they should have no more than 4 episodes of breakthrough pain a day.

The first dose of Instanyl is 50 micrograms (one spray of the lowest strength) in one nostril; this is increased as necessary until reaching the dose that gives the patient adequate pain relief. If there has been insufficient pain relief, the same dose can be given again at the earliest after 10 minutes.

The patient should be given Instanyl for a maximum of 4 episodes of breakthrough pain a day.

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

## **How does Instanyl work?**

The active substance in Instanyl, fentanyl, is an opioid. It is a well-known substance, which has been used to control pain for many years. In Instanyl, fentanyl is contained inside a nasal spray. When the patient sprays Instanyl into the nose, a dose of fentanyl is 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 Instanyl have been showed in studies?**

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, which showed that Instanyl was more effective than placebo (a dummy treatment) at treating breakthrough pain in cancer patients.

In one main study, 178 adult cancer patients with breakthrough pain took one spray of either Instanyl (50, 100 or 200 microgram) or placebo when they experienced breakthrough pain. The reduction in pain intensity after 10 minutes was between 1.8 and 2.7 points on an 11-point pain scale for patients who took Instanyl, compared with 1.4 for patients who took placebo. The number of patients who responded to treatment was also higher in the Instanyl group than in the placebo group. A patient's breakthrough pain was considered to have responded to treatment if there was a reduction of at least 2 points.

In another main study, 128 patients were given increasing doses of Instanyl until the adequate dose for pain relief was reached. The highest dose was 200 microgram given as one spray in one nostril and the patients were allowed to take a second spray after 10 minutes if there had been insufficient pain relief. Each patient then used the identified dose of Instanyl or placebo to treat breakthrough pain. The change in pain intensity after 10 minutes was between 2.0 and 2.7 points after receiving doses of Instanyl compared with 1.3 after receiving placebo. The number of breakthrough pain episodes that responded to treatment was also higher among patients who received Instanyl than those who received placebo.

In a third study, which involved 139 patients and compared Instanyl with 'transmucosal' fentanyl (absorbed through the lining of the mouth), patients who received Instanyl had faster pain relief than patients who received transmucosal fentanyl. Patients taking Instanyl were allowed to take a second spray 10 minutes after the first dose if there had been insufficient pain relief.

## **What are the risks associated with Instanyl?**

The most common side effects with Instanyl (which may affect up to 1 in 10 people) are somnolence (sleepiness), dizziness, headache, vertigo (a spinning sensation), flushing (reddening of the skin), hot flushes, throat irritation, nausea (feeling sick), vomiting and hyperhidrosis (excessive sweating). For the full list of side effects with Instanyl, see the package leaflet.

Instanyl 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. It must also not be used in patients who have had facial radiotherapy (treatment with radiation to the face) or who have recurrent episodes of epistaxis (nosebleeds). It

must not be used in patients treated with medicines containing sodium oxybate (used to treat narcolepsy, a sleep disorder). For the full list of restrictions, see the package leaflet.

### **Why is Instanyl authorised in the EU?**

Instanyl has been shown to provide rapid relief of pain in patients with cancer. Side effects are similar to those of other medicines containing fentanyl, and measures have been put in place to minimise the risk of misuse and overdose. The European Medicines Agency decided that Instanyl'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 Instanyl?**

The company that markets Instanyl will also provide educational materials to be supplied to patients, doctors and pharmacists, explaining the correct and safe use of the medicine.

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

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

### **Other information about Instanyl**

Instanyl received a marketing authorisation valid throughout the EU on 20 July 2009.

Further information on Instanyl can be found on the Agency's website: [ema.europa.eu/medicines/Human/EPAR/Instanyl](http://ema.europa.eu/medicines/Human/EPAR/Instanyl).

This overview was last updated in 03-2019