EMA/142006/2014
EMEA/H/C/000959

EPAR summary for the public

Instanyl

fentanyl

This is a summary of the European public assessment report (EPAR) for Instanyl. 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 Instanyl.

What is Instanyl?

Instanyl is a nasal spray that contains the active substance fentanyl (50, 100 and 200 micrograms per dose). It is available in single-dose containers and in multidose containers.

What is Instanyl used for?

Instanyl is 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.

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.

How is Instanyl used?

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 four episodes of breakthrough pain a day.

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

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 four episodes of breakthrough pain a day. See the package leaflet for further information.

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.

How has Instanyl been studied?

Because fentanyl has been in use for many years, the company presented data from scientific literature, as well as from studies that it had carried out. In one main study, 178 adult cancer patients with breakthrough pain took one spray of either Instanyl (50, 100 or 200 microgram) or placebo (a dummy treatment) when they experienced breakthrough pain. 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 ten minutes if there had been insufficient pain relief. Each patient then used the identified dose of Instanyl or placebo to treat breakthrough pain. The main measures of effectiveness for the two studies were the change in pain intensity as measured on a pain scale and the number of patients who responded to treatment after ten minutes. Each patient ranked their pain intensity on an 11-point scale. A patient's breakthrough pain was considered to have responded to treatment if there was a reduction of at least two points.

A third study involving 139 patients compared Instanyl with fentanyl as a 'transmucosal' tablet (absorbed through the lining of the mouth). The main measure of effectiveness was how quickly the patients had pain relief after experiencing breakthrough pain. The patients taking Instanyl were allowed to take a second spray ten minutes after the first dose if there had been insufficient pain relief.

What benefit has Instanyl shown during the studies?

Instanyl was more effective than placebo at treating breakthrough pain in cancer patients. In one of the main studies, the change in pain intensity after ten minutes was between 1.8 and 2.7 points on the 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.

In the second main study, the change in pain intensity after ten 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 the third study, patients who received Instanyl had faster pain relief than patients who received the comparator medicine.

What is the risk associated with Instanyl?

The most common side effects with Instanyl (seen in between 1 and 10 patients in 100) are somnolence (sleepiness), dizziness, headache, vertigo (a spinning sensation), flushing (reddening), hot flushes, throat irritation, nausea (feeling sick), vomiting and hyperhidrosis (excessive sweating). For the full list of all side effects reported 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) or who have recurrent episodes of epistaxis (nosebleeds). For the full list of restrictions, see the package leaflet.

Why has Instanyl been approved?

The CHMP decided that Instanyl'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 Instanyl?

A risk management plan has been developed to ensure that Instanyl 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 Instanyl, including the appropriate precautions to be followed by healthcare professionals and patients.

The company that makes Instanyl will also provide educational materials in all Member States to be supplied to patients, doctors and pharmacists, to explain the correct and safe use of the medicine.

Other information about Instanyl

The European Commission granted a marketing authorisation valid throughout the European Union for Instanyl on 20 July 2009.

The full EPAR for Instanyl 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 Instanyl, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 03-2014