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EPAR summary for the public

Ionsys

fentanyl

This is a summary of the European public assessment report (EPAR) for Ionsys. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Ionsys.

For practical information about using Ionsys, patients should read the package leaflet or contact their doctor or pharmacist.

What is Ionsys and what is it used for?

Ionsys is a transdermal system used to control moderate to severe pain after an operation in adults who are in hospital. It contains the active substance fentanyl.

How is Ionsys used?

Ionsys can only be used in hospital. Treatment should be given under the guidance of a doctor experienced in the use of opioids such as fentanyl. Due to the potential of abuse with fentanyl, the doctor should evaluate whether the patient has a history of drug abuse before giving Ionsys and if so follow the patient closely.

Ionsys transdermal system delivers the active substance, fentanyl, through the skin. A doctor or a nurse applies the transdermal system to the patient's skin on the chest or upper arm. When in pain, the patient uses a button on the Ionsys system to start the delivery of a dose of fentanyl (40 micrograms). Ionsys can be used up to six times in one hour, but for no more than 80 doses within a 24-hour period. The system will stop working 24 hours after the first dose or after 80 doses have been delivered, whichever comes first. Ionsys must be removed by a doctor or nurse and before the patient leaves the hospital. For further information see the package leaflet.

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How does Ionsys work?

Ionsys contains the active substance fentanyl, which is a strong opioid painkiller. It is a well-known substance, which has been used to control pain for many years. When the patient activates Ionsys, a dose of fentanyl moves through the skin into the bloodstream. Once in the bloodstream, fentanyl acts on receptors in the brain and spinal cord to control pain.

What benefits of Ionsys have been shown in studies?

Ionsys has been shown to be effective at controlling pain after an operation in seven main studies involving a total of around 3,300 patients. In three of the studies, Ionsys was compared with placebo (a dummy system). The proportion of patients who stopped treatment because their pain was not controlled was lower in patients treated with Ionsys (and ranged between 8% and 27%) than in those treated with placebo (where it ranged between 40 and 57%).

The other four studies compared Ionsys with morphine given by injection into a vein, and looked at the number of patients who judged their pain relief as 'good' or 'excellent'. These studies showed that Ionsys is as at least as effective as morphine at controlling pain.

All the studies described above were carried out with a different delivery device, which was recalled from the market in 2008 because of a defect in the design of the system. The defect has been corrected in the new system.

What are the risks associated with Ionsys?

The most common side effects with Ionsys (which may affect more than 1 in 10 people) are nausea (feeling sick), vomiting and erythema (redness) at the application site. These are usually mild to moderate in severity. The most serious side effects are hypotension (low blood pressure) and apnoea (pauses in breathing) and patients should be closely monitored for these. For the full list of all side effects reported with Ionsys, see the package leaflet.

Ionsys must not be used in patients with severe respiratory depression (breathing problems) or with a rare condition called cystic fibrosis. For the full list of restrictions, see the package leaflet.

Why is Ionsys approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Ionsys' benefits are greater than its risks and recommended that it be approved for use in the EU. The CHMP considered Ionsys to be effective at managing pain after an operation and the fact that is not given by injection could be of benefit to patients. The safety profile is acceptable and is similar to morphine given by injection into a vein.

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

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

In addition, the company that market Ionsys will provide all healthcare professionals expected to use Ionsys educational material with information on the adequate use of the product.

Further information can be found in the summary of the risk management plan.

Other information about Ionsys

The European Commission granted a marketing authorisation valid throughout the European Union for Ionsys on 19 November 2015.

The full EPAR and risk management plan summary for Ionsys 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 Ionsys, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 11-2015.