European Medicines Agency

EMEA/H/C/612

EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

IONSYS

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is IONSYS?
IONSYS is an iontophoretic transdermal system (ITS), which delivers the active substance, fentanyl hydrochloride, into the body through the skin.

What is IONSYS used for?
IONSYS is used to control pain after an operation, in patients who are in hospital.

How is IONSYS used?
IONSYS is given to the patient after an operation. It is given using a system that is operated by the patient. 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. It must then be removed by a doctor or nurse.

How does IONSYS work?
IONSYS contain the active ingredient fentanyl, which is a strong painkiller. Fentanyl is derived from opium. It is a well-known substance, which has been used to control pain for many years. The fentanyl is contained inside a reservoir. When the patient activates IONSYS, a small electrical current moves a dose of fentanyl from the reservoir through the skin and into the bloodstream. Once in the bloodstream, fentanyl acts on receptors in the brain and spinal cord to prevent pain.

How has IONSYS been studied?
The effects of IONSYS were first tested in experimental models before being studied in humans.
Four main studies were performed in about 800 patients after an operation. In three of them, IONSYS was compared with placebo (a transdermal system identical to IONSYS, but from which the medicine could not be released). These studies measured the number of patients who stopped treatment because they were not getting enough pain relief.
The fourth study compared IONSYS to morphine given by injection into a vein, and looked at the number of patients who judged their pain relief as 'good' or 'excellent'.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 85 45
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

What benefit has IONSYS shown during the studies?
In the studies where IONSYS was compared to placebo, the proportion of patients who stopped treatment because their pain was not controlled was lower in patients treated with IONSYS than those treated with placebo. These results show that IONSYS has a benefit in controlling pain after an operation.
The results of the study comparing IONSYS with morphine were insufficient to determine whether the two medicines were of similar effectiveness in relieving pain or not.

What is the risk associated with IONSYS?
The most common side effects with IONSYS (seen in more than 1 patient in 10) are nausea (feeling sick), vomiting, headache and erythema (redness of the skin) at the site of application. For the full list of all side effects reported with IONSYS, see the Package Leaflet.
Fentanyl, the active substance in IONSYS, can be abused. However, the risk with IONSYS is low, as the medicine is for short-term use.
IONSYS must only be used in hospital, and it must not be used in patients who have respiratory problems (such as breathing difficulties), or heart, liver or kidney problems. For the full list of restrictions, see the Package Leaflet.

Why has IONSYS been approved?
The Committee for Medicinal Products for Human Use (CHMP) concluded that IONSYS offers potential benefits compared to systems where the pain relief is given via a vein: it is non-invasive, needle-free and pre-programmed, and it can be activated by the patient.
Therefore, the Committee decided that IONSYS's benefits are greater than its risks for the management of acute moderate to severe post-operative pain for use in a hospital setting only. The Committee recommended that IONSYS be given marketing authorisation.

Which measures are being taken to ensure the safe use of IONSYS?
The company that makes IONSYS will monitor the key safety risks associated with IONSYS such as overdose, abuse, addiction or misuse, and will provide an educational plan for patients, doctors and healthcare providers, aimed at minimising the risk and supporting the safe and effective use of the medicine.

Other information about IONSYS:
The European Commission granted a marketing authorisation valid throughout the European Union for IONSYS to Janssen-Cilag International NV on 24 January 2006.

The full EPAR for IONSYS can be found here.

This summary was last updated in 10-2007.