



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Measures to ensure that Ionsys is handled and used correctly

Educational material will be provided to healthcare professionals who will use the transdermal system

Overdose, abuse and accidental exposure are important risks of Ionsys and other opioid medicines. They can lead to serious adverse effects such as difficulty breathing. Healthcare professionals who are expected to prescribe, dispense or administer Ionsys will be provided with educational material on the correct use of the transdermal system. Healthcare professionals should ensure that patients understand how to operate the system.

Ionsys transdermal system is applied to the skin and provides on-demand fentanyl to control moderate to severe pain after an operation in adults. It can only be used in hospital. Ionsys is activated by the patient, who controls how much medicine they receive. When in pain, the patient presses a button twice on the Ionsys system to start the delivery of one dose (40 microgram) of fentanyl over 10 minutes.

The educational material is to help healthcare professionals minimise the risk of overdose by ensuring that patients do not use unnecessary doses of Ionsys. It will also help healthcare professionals to recognise when the system is not working properly and tell them how the medicine should be disposed of in order to avoid accidental contact. The material includes the package leaflet for the patients, with information on how Ionsys works and its safety.

### Information for patients

- A doctor or a nurse will apply Ionsys transdermal system to the skin on your chest or upper arm, and will show you how to use the system.
- You will start the delivery of a dose of fentanyl by pressing a button on the Ionsys system twice within 3 seconds. After pressing the button, the system will deliver one dose of fentanyl over 10 minutes. There is a gap of 10 minutes before another dose can be activated.
- Only press the button when you need pain relief. Do not let anyone else press the button.
- If you feel faint or if you have difficulty breathing while using Ionsys, tell your doctor or nurse immediately, as this may be a sign of overdose.
- If you think that the system is not working properly, tell your doctor or nurse immediately.



- Fentanyl is a strong opioid painkiller. Do not share Ionsys with anybody else, as the fentanyl in Ionsys may be fatal for people to whom it was not prescribed.
- Do not touch the gels in the Ionsys transdermal system. If you (or anyone else) accidentally touch the gels in Ionsys tell your doctor or nurse straightaway and wash your hands with water only (not soap).
- Your doctor or nurse will remove Ionsys before you leave the hospital. They will make sure that Ionsys is disposed of safely, as some fentanyl remains in the Ionsys system after use and may potentially be dangerous.
- If you have any questions about your treatment, speak to your doctor or nurse.

### **Information for healthcare professionals**

- Ionsys should only be used to control moderate to severe post-operative pain in adults who are in hospital.
- The Ionsys system should be placed on the skin and removed by a healthcare professional only, who should ensure that the patient understands how to operate the system.
- Patients should be evaluated for a history of drug abuse before starting Ionsys treatment, and if they have a history of drug abuse they should be monitored closely.
- Healthcare professionals should tell patients that they should press the dosing button only when they need pain relief. They should not let anyone else press the dosing button. Patients should be assessed for signs of overdose.
- Gloves must be worn when handling Ionsys including during assembly, application, removal and disposal. Any accidental exposure of skin to the hydrogels should be treated by rinsing the affected area with water only (i.e. not soap).
- Healthcare professionals should tell patients that if they suspect a device failure or malfunction, they must inform a healthcare professional immediately. Healthcare professionals should read the 'Troubleshooting guide' and if device failure or malfunction is suspected Ionsys should be removed immediately from the patient and the company that markets Ionsys should be contacted straightaway.
- A residual amount of fentanyl remains in the Ionsys system after use and may potentially be dangerous. Healthcare professionals should therefore ensure that Ionsys is disposed of appropriately, in accordance with local requirements for opioid medicines and hospital procedures for battery waste. This is described in the 'Instructions for use and disposal'.

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### **More about the medicine**

Ionsys is a transdermal system used to control moderate to severe pain after an operation in adults who are in hospital. When the patient activates Ionsys, a dose of the active substance, fentanyl, moves through the skin into the bloodstream. Fentanyl is a strong opioid painkiller. Once in the bloodstream, fentanyl acts on receptors in the brain and spinal cord to control pain.

More information on Ionsys can be found on the Agency's website: [ema.europa.eu/Find/medicine/Human\\_medicines/European\\_public\\_assessment\\_reports](https://www.ema.europa.eu/Find/medicine/Human_medicines/European_public_assessment_reports).