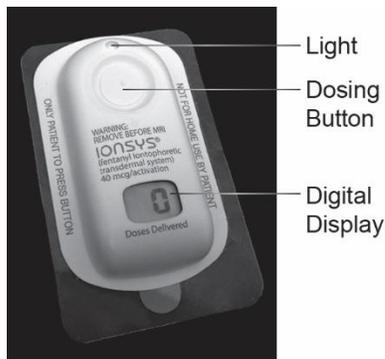


IONSYS® Medication Guide
IONSYS® (eye-AHN-sis)
(fentanyl iontophoretic transdermal system) CII

IONSYS is:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage acute postoperative pain, when other pain treatments such as non-opioid pain medicines do not treat your pain well enough or you cannot tolerate them.
- An opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to death.
- A patient-controlled medicine system that sticks to the skin. It will be applied by your healthcare provider on your upper outer arm or chest.



Important information about IONSYS:

Get emergency help right away if you use too much fentanyl, the active ingredient in IONSYS (overdose). Only you should press the button on IONSYS. When you first start using IONSYS, serious or life-threatening breathing problems that can lead to death may occur.

- Never give anyone else your IONSYS. They could die from using it. Store IONSYS away from children and in a safe place to prevent stealing or abuse. Selling or giving away IONSYS is against the law.
- **IONSYS is only for use in the hospital. Do not leave the hospital with IONSYS on your skin.**
- Using IONSYS with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.

Do not use IONSYS if you have:

- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or have narrowing of the stomach or intestines.
- an allergy to fentanyl or Cepacol® (cetylpyridinium chloride).

Before using IONSYS, tell your healthcare provider if you have a history of:

- head injury, seizures
- liver, kidney, thyroid problems
- problems urinating
- pancreas or gallbladder problems
- abuse of street or prescription drugs, alcohol addiction, or mental health problems.

Tell your healthcare provider if you are:

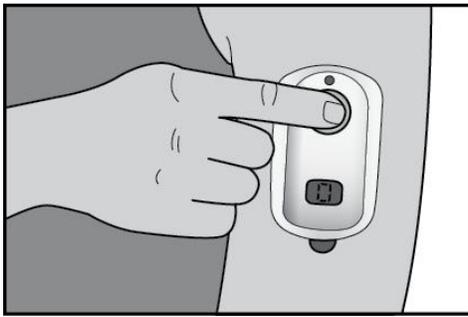
- **pregnant or planning to become pregnant.** Prolonged use of IONSYS during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated.
- **breastfeeding.** IONSYS passes into breast milk and may harm your baby.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Using IONSYS with certain other medicines can cause serious side effects that could lead to death.

Your healthcare provider:

- will tell you about IONSYS and teach you how to use it.
- will put IONSYS on the skin (of your chest or upper outer arm) after your surgery
- will control pain from your surgery with other pain medicines until you are awake enough to use IONSYS
- will check you for side effects from IONSYS.
- must replace your IONSYS as needed. You should not replace your IONSYS yourself.
- will remove your IONSYS before you leave the hospital. **Do not leave the hospital with IONSYS on your skin.**

How do I use IONSYS?

- You can push the IONSYS dosing button when you are experiencing pain or just before you do an activity that may increase your pain - such as physical therapy or getting out of bed.
- To get a dose of pain medicine from IONSYS, **press and release the dosing button twice within 3 seconds.**



- When you push the dosing button you will hear a single beep and the green light will start blinking quickly. The green light will continue to blink quickly for the 10 minutes it takes to deliver a dose of IONSYS.
- During this time, IONSYS will not deliver another dose even if you press the dosing button again.
- IONSYS can only be activated every 10 minutes.
- When IONSYS is finished delivering a dose, the green light will start blinking slowly. This means you can give yourself more pain medicine, if needed. Just press and release the dosing button twice within 3 seconds like you did before. The digital display will tell your healthcare provider how many doses you have received. Each IONSYS may be used for up to 24 hours or a maximum of 80 doses, whichever comes first.
- If IONSYS starts beeping at any time tell your healthcare provider right away.

Your healthcare provider will check your IONSYS to make sure it is working properly.

When using IONSYS:

- Tell your healthcare provider if the dose you are using does not control your pain.
- Do not let anyone else press the IONSYS dosing button for you. **You are the only person who should push the dosing button.**
- Do not touch IONSYS if it falls off of your skin. Tell your healthcare provider right away if your IONSYS comes off of your skin. Rinse your hands with water (do not use soap) right away if you accidentally touch the sticky side of IONSYS, and tell your healthcare provider right away.
- Do not let others touch IONSYS.
- Do not remove or replace IONSYS yourself.
- Do not leave the hospital with IONSYS on your skin. **Make sure your healthcare provider removes your IONSYS before you leave the hospital.**
- **IONSYS is MR Unsafe and should not be brought into an MRI environment.**

Tell your healthcare provider right away if:

- you have any questions about IONSYS
- you are still having pain
- IONSYS falls off your skin
- you have trouble using IONSYS

While using IONSYS DO NOT:

- Drive or operate heavy machinery, until you know how IONSYS affects you. IONSYS can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or over-the-counter medicines that contain alcohol. Using products containing alcohol during treatment with IONSYS may cause you to overdose and die.

The possible side effects of IONSYS:

- constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain. Tell your healthcare provider if you have any of these symptoms and they are severe.

Tell your health care provider immediately if you have:

- trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue, or throat, extreme drowsiness, lightheadedness when changing positions, feeling faint, agitation, high body temperature, trouble walking, stiff muscles, or mental changes such as confusion.

These are not all the possible side effects of IONSYS. Ask your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. **For more information go to dailymed.nlm.nih.gov.**

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