

Onsolis (fentanyl buccal soluble film)

What is Onsolis?

Onsolis is a new drug approved by the FDA in July of 2009. Onsolis contains fentanyl, an opioid pain reliever, in a small film (about the size of a dime or nickel) that sticks to the inside of your cheek and eventually dissolves within 15 to 30 minutes after it is applied. Onsolis is used to manage breakthrough pain (flare-up of pain occurring in patients with otherwise stable, constant pain) in patients with cancer, 18 years of age and older, who are already using another opioid pain medicine around-the-clock and whose body is used to the medicine (opioid-tolerant). Onsolis comes in a foil package and is available in dosage strengths of 200 mcg, 400 mcg, 600 mcg, 800 mcg and 1200 mcg.

Is Onsolis a generic version of other fentanyl products? Can it be substituted for other similar pain drugs?

NO. Onsolis is NOT a generic version of any other transmucosal fentanyl product. Onsolis cannot be substituted for any other fentanyl product. Substantial differences exist in how Onsolis is absorbed compared to other oral transmucosal fentanyl products. Substitution of Onsolis for any other oral transmucosal fentanyl product may result in fatal overdose.

How will Onsolis be supplied?

Oral transmucosal fentanyl products are potent opioids that are highly effective in treating pain, but also have a very high risk of death when they are administered incorrectly, especially to patients who are not opioid tolerant. Therefore, FDA is requiring restricted distribution programs for Onsolis. Key points regarding Onsolis and other fentanyl-based drug products:

- The indications for the transmucosal fentanyl products are unique. Onsolis, Actiq and Fentora are indicated for breakthrough cancer pain in patients who are on around-the-clock opioids and are considered opioid-tolerant. The misuse and abuse of these drugs in opioid nontolerant patients or patients who are not taking opioids daily has led to deaths.
- These products are not absorbed in the body the same way, and as a result, cannot be substituted for one another. Medication errors have been reported with Fentora being substituted for Actiq, even though it is stated in a boxed warning not to do so. This experience in light of a third oral transmucosal fentanyl coming onto the market warrants additional steps to reduce the likelihood of inappropriate substitution of these drugs.
- Fentanyl has become highly sought after by abusers. There is concern that as more of these products reach the market, failure to anticipate and prevent misuse and abuse could result significant overdose or death.

Source: U.S. Food and Drug Administration