

SUBSYS® (FENTANYL SUBLINGUAL SPRAY)

Available 100,200,400,600,800,1200,1600mcg

INDICATIONS and USAGE:

“SUBSYS is indicated for the management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine daily, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oral oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid daily for a week or longer. Patients must remain on around-the-clock opioids when taking SUBSYS.

This product must not be used in opioid non-tolerant patients because life-threatening respiratory depression and death could occur at any dose in patients not on a chronic regimen of opioids. For this reason, SUBSYS is contraindicated in the management of acute or postoperative pain.

SUBSYS is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

Limitations of Use

As part of the Transmucosal Immediate-Release Fentanyl (TIRF) REMS ACCESS Program, SUBSYS may be dispensed only to outpatients enrolled in the program. For inpatient administration (e.g. hospitals, hospices, and long-term care facilities that prescribe for inpatient use) of SUBSYS, patient enrollment is not required.”¹

Criteria for Approval:

1. The patient is a 18 years or older; **AND**
2. The patient is being treated for cancer pain; **AND**
3. The patient is opioid tolerant as described above; **AND**
4. The patient is receiving around-the-clock opioid therapy; **AND**
5. Patients and provider must comply with the TIRF REMS ACCESS program if applicable.
 - a. <https://www.tirfremssaccess.com/TirfUI/remss/home.action>

Length of Authorization:

1. Authorization may be approved for **6 months**.

Dispensing Limit:

1. The dispensing limit is a 30 day supply of medication

References:

¹ Subsys® package insert is available at: <<http://subsyspray.com/assets/Prescribing%20Information.pdf> >
Accessed 12/11/12

Subsys criteria

Version 1

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