# The FOCUS™ Program for ONSOLIS™

Onsolis™ fentanyl buccal soluble film ©

Information for prescribers | Information for pharmacists | Information for patients

For information on the FOCUS™ Program, call 1-877-466-7654 (1-877-4ONSOLIS).

Please see full prescribing information including boxed warnings by clicking the link below.

**Important Safety Information**

The most serious adverse reactions associated with all opioids are respiratory depression (potentially leading to apnea or respiratory arrest), circulatory depression, hypotension, and shock. Follow all patients for symptoms of respiratory depression. In ONSOLIS™ trials, the most common adverse reactions were: nausea, vomiting, dizziness, anemia, dehydration, peripheral edema, dyspnea, and somnolence.

**WARNINGS: IMPORTANCE OF PROPER PATIENT SELECTION and POTENTIAL FOR ABUSE**

**ONSOLIS contains fentanyl, an opioid agonist and a Schedule II controlled substance, with abuse liability similar to other opioid analgesics. This should be considered when prescribing or dispensing ONSOLIS in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse or diversion. Schedule II opioid substances, which include morphine, oxycodone, hydromorphone, oxymorphone, and methadone, have the highest potential for abuse and risk of fatal overdose due to respiratory depression.**

**Serious adverse events, including deaths, in patients treated with other oral transmucosal fentanyl products have been reported. Deaths occurred as a result of improper patient selection (e.g., use in opioid non-tolerant patients) and/or improper dosing. The substitution of ONSOLIS for any other fentanyl product may result in fatal overdose.**

**ONSOLIS is indicated only for the management of breakthrough pain in patients with cancer, 18 years of age and older, who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.** Patients considered opioid tolerant are those who are taking at least: 60 mg oral morphine/day, 25 mcg transdermal fentanyl/hour, 30 mg of oral oxycodone/day, 8 mg oral hydromorphone/day, 25 mg oral oxymorphone/day, or an equianalgesic dose of another opioid for one week or longer.

**ONSOLIS is contraindicated for use in opioid non-tolerant patients including those using opioids intermittently, on an as needed basis.**

**ONSOLIS is contraindicated in the management of acute or postoperative pain, including headache/migraine, dental pain, or use in the emergency room. Life-threatening respiratory depression could occur at any dose in opioid non-tolerant patients. Deaths have occurred in opioid non-tolerant patients treated with other fentanyl products.**

**When prescribing, do not convert patients on a mcg per mcg basis from any other oral transmucosal fentanyl product to ONSOLIS. Patients beginning treatment with ONSOLIS must begin with titration from the 200 mcg dose [see *Dosage and Administration* (2)].**

**When dispensing, do not substitute an ONSOLIS prescription for any other fentanyl product. Substantial differences exist in the pharmacokinetic profile of ONSOLIS compared to other fentanyl products that result in clinically important differences in the extent of absorption of fentanyl. As a result of these differences, the substitution of ONSOLIS for any other fentanyl product may result in fatal overdose.**

Prescriber Name (print): _____

**Prescriber Knowledge Assessment**

5. During titration or maintenance treatment, the interval between successive doses of ONSOLIS™ should be at least:
   - ☐ A. 15 minutes
   - ☐ B. 1 hour
   - ☐ C. 2 hours
   - ☐ D. 6 hours

6. Which of the following may help assess the risk of addiction?
   - ☐ A. history of personal or familial problems with alcohol or drugs
   - ☐ B. history of prescription drug misuse
   - ☐ C. screening instruments such as the Screener and Opioid Assessment for Patients with Pain (SOAPP)
   - ☐ D. all of the above

7. TRUE OR FALSE: ONSOLIS™ must be kept out of the reach of children because it contains a medicine in an amount which can be fatal to children.
   - ☐ A. True
   - ☐ B. False

8. TRUE OR FALSE: Use of ONSOLIS™ with CYP3A4 inhibitors (such as erythromycin, ketoconazole, and certain protease inhibitors) may require dosage adjustment; otherwise such use may cause potentially fatal respiratory depression.
   - ☐ A. True
   - ☐ B. False

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Special care must be used when dosing ONSOLIS. If the breakthrough pain episode is not relieved, patients should wait at least 2 hours before taking another dose [see *Dosage and Administration* (2)].

ONSOLIS is intended to be used only in the of care of opioid tolerant patients with cancer and only by healthcare professionals who are knowledgeable of, and skilled in, the use of Schedule II opioids to treat cancer pain.

**Patients and their caregivers must be instructed that ONSOLIS contains a medicine in an amount which can be fatal in children, in individuals for whom it is not prescribed, and in those who are not opioid tolerant. All ONSOLIS films must be kept out of the reach of children [see *Patient Counseling Information* (17)].**

The concomitant use of ONSOLIS with CYP3A4 inhibitors may result in an increase in fentanyl plasma concentrations and may cause potentially fatal respiratory depression [see *Drug Interactions* (7)].

Because of the risk for misuse, abuse, and overdose, ONSOLIS is available only through a restricted distribution program, called the FOCUS Program. Under the FOCUS Program, only prescribers, pharmacies, and patients registered with the program are able to prescribe, dispense, and receive ONSOLIS. To enroll in the FOCUS Program, call 1-877-466-7654 (1-877-4ONSOLIS) or visit www.OnsolisFocus.com [see *Warnings and Precautions* (5.3.1)].



MEDA PHARMACEUTICALS

# The FOCUS™ Program for ONSOLIS™

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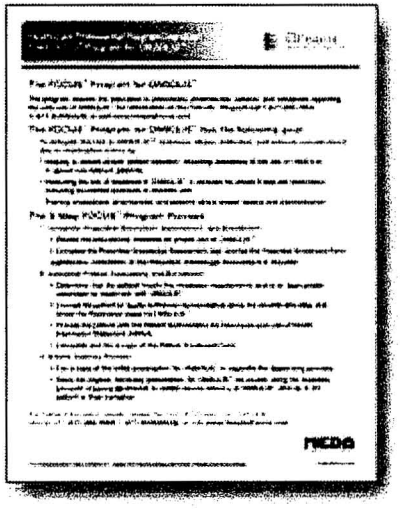
## Information for prescribers

### Healthcare Professional Program Overview



Click to open

In order to enroll yourself and your patient and initiate ONSOLIS™ prescribing, you must complete the 3-Step FOCUS™ Program Process.

Please see full prescribing information including boxed warnings by clicking the link below.

Home

Prescriber Program Overview

Prescriber Education

REMS

Prescriber Enrollment Form

Patient Program Overview

Medication Guide

Patient Enrollment Form

# Information for prescribers

**Prescriber Education, Assessment, and Enrollment**

Before you can enroll in the FOCUS™ Program for ONSOLIS™, you must complete the prescriber education and Knowledge Assessment. Satisfactory completion of the knowledge assessment is required. Review the information in each of the following sections to complete your education and enrollment.

- **Proper Patient Selection:** Indications and contraindications
- **Dosing & Administration:** Maintenance, titration, dosage adjustments
- **General Opioid Use:** Good medical practice, risk assessment
- **Risks of ONSOLIS™:** Overdose and addiction
- **Program Overview**

**Proper Patient Selection**

**ONSOLIS™ (fentanyl buccal soluble film) is an opioid analgesic indicated only for the management of breakthrough pain in patients with cancer, 18 years of age and older, who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.** Patients considered opioid tolerant are those who are taking at least: 60 mg oral morphine/day, 25 mcg transdermal fentanyl/hour, 30 mg oral oxycodone/day, 8 mg oral hydromorphone/day, 25 mg oral oxymorphone/day, or an equianalgesic dose of another opioid for one week or longer.

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Home

Prescriber Program Overview

Prescriber Education

REMS

Prescriber Enrollment Form

Patient Program Overview

Medication Guide

Patient Enrollment Form

# Information for prescribers

**Proper Patient Selection, cont'd**

ONSOLIS™ is **contraindicated** for use in opioid non-tolerant patients including those using opioids intermittently, on an as needed basis.

ONSOLIS™ is **contraindicated** in the management of acute or postoperative pain, including headache/migraine, dental pain, or use in the emergency room. Life-threatening respiratory depression could occur at any dose in opioid non-tolerant patients. Deaths have occurred in opioid non-tolerant patients treated with other fentanyl products.

Patients and their caregivers must be instructed that ONSOLIS™ contains a medicine in an amount which can be fatal in children, in individuals for whom it is not prescribed, and in those who are not opioid tolerant. All ONSOLIS™ films must be kept out of the reach of children. All unneeded ONSOLIS™ films should be disposed of by removing from the foil package and flushing down a toilet.

ONSOLIS™ is intended to be used only in the care of opioid tolerant patients with cancer and only by healthcare professionals who are knowledgeable of, and skilled in the use of, Schedule II opioids to treat cancer pain.

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Home

Prescriber Program Overview

Prescriber Education

REMS

Prescriber Enrollment Form

Patient Program Overview

Medication Guide

Patient Enrollment Form

# Information for prescribers

## Dosing & Administration

***Appropriate product dosing and administration***

As with all opioids, the safety of patients using such products is dependent on healthcare professionals prescribing them in strict conformity with their approved labeling with respect to patient selection, dosing, and proper conditions for use.

Only prescribers enrolled in the FOCUS program may prescribe ONSOLIS™.

***Dose titration***

The goal of dose titration is to find the individual patient's effective and tolerable dose. The dose of ONSOLIS™ is not predicted from the daily maintenance dose of opioid used to manage the persistent cancer pain and MUST be determined by dose titration.

Starting Dose: Individually titrate ONSOLIS™ to a dose that provides adequate analgesia with tolerable side effects. All patients MUST begin treatment using one 200 mcg ONSOLIS™ film.

Due to differences in pharmacokinetic properties and individual variability, **patients switching from another oral transmucosal fentanyl product must be started on no greater than 200 mcg of ONSOLIS™. When prescribing, do not switch patients on a mcg per mcg basis from any other oral transmucosal fentanyl**

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Home

Prescriber Program Overview

Prescriber Education

REMS

Prescriber Enrollment Form

Patient Program Overview

Medication Guide

Patient Enrollment Form

# Information for prescribers

**Dosing & Administration, cont'd**

**product to ONSOLIS™** as ONSOLIS™ is not equivalent on a mcg per mcg basis with any other fentanyl product. ONSOLIS™ is NOT a generic version of any other oral transmucosal fentanyl product.

From the initial dose, closely follow patients and change the dosage level until the patient reaches a dose that provides adequate analgesia.

If adequate pain relief *is not achieved* after **one** 200 mcg ONSOLIS™ film, titrate using multiples of the 200 mcg ONSOLIS™ film (for doses of 400, 600, or 800 mcg). Increase the dose level by 200 mcg in each subsequent episode until the patient reaches a dose that provides adequate analgesia with tolerable side effects. Do not use more than four of the 200 mcg ONSOLIS™ films simultaneously. When multiple 200 mcg ONSOLIS™ films are used, they **should not be placed on top of each other** and may be placed on both sides of the mouth.

If adequate pain relief *is not achieved* after 800 mcg ONSOLIS™ (ie, **four** 200 mcg ONSOLIS™ films), and the patient has tolerated the 800 mcg dose, treat the next episode by using **one** 1200 mcg ONSOLIS™ film. Doses above 1200 mcg ONSOLIS™ should not be used.

Once adequate pain relief *is achieved* with a dose between 200 and 800 mcg ONSOLIS™, the patient should use or safely dispose of all remaining 200 mcg ONSOLIS™ films. Patients who require 1200 mcg

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Home

Prescriber Program Overview

Prescriber Education

REMS

Prescriber Enrollment Form

Patient Program Overview

Medication Guide

Patient Enrollment Form

# Information for prescribers

**Dosing & Administration, cont'd**

ONSOLIS™, should dispose of all remaining unused 200 mcg ONSOLIS™ films. The patient should then get a prescription for ONSOLIS™ films of the dose determined by titration (ie, 200, 400, 600, 800, or 1200 mcg) to treat subsequent episodes.

**Single doses should be separated by at least 2 hours. ONSOLIS™ should only be used once per breakthrough cancer pain episode, ie, ONSOLIS™ should not be redosed within an episode.**

During any episode of breakthrough cancer pain, if adequate pain relief *is not achieved* after ONSOLIS™, the patient may use a rescue medication (after 30 minutes) as directed by their healthcare provider.

*Please see full prescribing information including boxed warnings by clicking the link below.*