



Important Prescribing Information About ONSOLIS™ (fentanyl buccal soluble film).

Dear Prescriber:

MEDA Pharmaceuticals Inc. is introducing ONSOLIS™, a new treatment indicated only for breakthrough pain in patients with cancer, 18 years of age and older. ONSOLIS™ can only be used in patients 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.

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 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.

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.

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.

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.

The concomitant use of ONSOLIS™ with CYP3A4 inhibitors may result in an increase in fentanyl plasma concentrations and may cause potentially fatal respiratory depression.

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.

The FOCUS™ Program has been implemented to mitigate the risk of ONSOLIS™ overdose, abuse, addiction, and serious complications due to medication errors by: helping to assure proper patient selection, including avoidance of the use of ONSOLIS™ in opioid non-tolerant patients; reducing the risk of exposure to ONSOLIS™ in persons for whom it was not prescribed, including accidental exposure in children; and training prescribers, pharmacists, and patients about proper dosing and administration. Enrolled patients receive ONSOLIS™ directly from a specialty pharmacy, which delivers the medication via a secure, traceable courier.

Adverse Reactions

The adverse reactions seen with ONSOLIS™ are typical opioid side effects in a population with cancer. Frequently, opioid-associated adverse reactions will cease or decrease in intensity with continued use of ONSOLIS™. **Expect opioid side effects and manage them accordingly.** The most serious adverse reactions associated with all opioids including ONSOLIS™ are respiratory depression (potentially leading to apnea or respiratory arrest), circulatory depression, hypotension, and shock. Follow all patients for symptoms of respiratory depression.

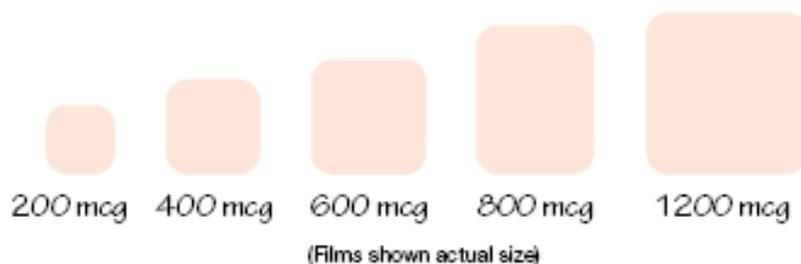
The most common adverse reactions are: nausea, vomiting, dizziness, anemia, dehydration, peripheral edema, dyspnea, and somnolence.

We appreciate your time and consideration and look forward to offering you and your patients continued support.

Sincerely,

[signature]

[name, title, MEDA Pharmaceuticals Inc.]



Please see accompanying Full Prescribing Information, including BOXED WARNINGS.

The FOCUS™ Program for ONSOLIS™

The program requires the education of prescribers, pharmacists, patients, and caregivers regarding the safe use of ONSOLIS™. For information on the FOCUS™ Program call 1-877-466-7654 (1-877-4ONSOLIS) or visit www.OnsolisFocus.com.

The FOCUS™ Program for ONSOLIS™ has the following goal:

To mitigate the risk of ONSOLIS™ overdose, abuse, addiction, and serious complications due to medication errors by:

- Helping to assure proper patient selection, including avoidance of the use of ONSOLIS™ in opioid non-tolerant patients;
- Reducing the risk of exposure to ONSOLIS™ in persons for whom it was not prescribed, including accidental exposure in children; and
- Training prescribers, pharmacists, and patients about proper dosing and administration.

The 3-Step FOCUS™ Program Process

1. Complete Prescriber Education, Assessment, and Enrollment

- Review the educational materials on proper use of ONSOLIS™
- Complete the Prescriber Knowledge Assessment; sign and fax the Prescriber Enrollment Form
Satisfactory completion of the Prescriber Knowledge Assessment is required

2. Complete Patient Counseling and Enrollment

- Determine that the patient meets the necessary requirements and is an appropriate candidate for treatment with ONSOLIS™
- Counsel the patient (or legally authorized representative) about the benefits and risks, and review the Medication Guide for ONSOLIS™
- Provide the patient with the Patient Authorization for Disclosure and Use of Health Information Statement (HIPAA)
- Complete and fax a copy of the Patient Enrollment Form

3. Initiate Delivery Process

- Fax a copy of the initial prescription for ONSOLIS™ to expedite the dispensing process
- Send the original, hardcopy prescription for ONSOLIS™ via courier using the supplied, pre-paid shipping label/airbill to initiate secure delivery of ONSOLIS™ directly to the patient or their caregiver

For further information please contact the **FOCUS™ Program for ONSOLIS™** directly at **1-877-466-7654 (1-877-4ONSOLIS)** or visit www.OnsolisFocus.com

Prescriber Enrollment Form

The FOCUS™ Program for ONSOLIS™



I understand that ONSOLIS™ is available only through the FOCUS™ Program, I must comply with the program requirements, and acknowledge that:

1. I have reviewed the Prescribing Information for ONSOLIS™ and the educational materials for the FOCUS™ Program. I have completed the Prescriber Knowledge Assessment, and I understand the risks and benefits of chronic opioid therapy.
2. I understand that ONSOLIS™ can be abused and this should be considered when prescribing or dispensing ONSOLIS™ in situations where I am concerned about an increased risk of misuse, abuse, or overdose, whether accidental or intentional.
3. I understand that 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.
4. I understand that ONSOLIS™ is not bioequivalent with any other oral transmucosal fentanyl citrate product and therefore should not be converted from other oral transmucosal fentanyl citrate products on a microgram-per-microgram basis.
5. I will prescribe ONSOLIS™ to patients only after obtaining a signed FOCUS™ Program for ONSOLIS™ Patient Enrollment Form for each patient that documents the following safe use conditions:
 - a. Patients have been using around-the-clock opioid analgesia for at least 1 week;
 - b. Patients are opioid tolerant: patients considered opioid tolerant are those who are regularly 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;
 - c. Patients or legally authorized representatives have been counseled about the risks and benefits and appropriate use of ONSOLIS™, and about the risk of overdose due to giving ONSOLIS™ to someone for whom it has not been prescribed as described in the Medication Guide for ONSOLIS™; and
 - d. Patients or legally authorized representatives have been provided and reviewed the Medication Guide for ONSOLIS™.
6. I will provide a completed, signed copy of the patient enrollment form for each patient to the FOCUS™ Program for ONSOLIS™.
7. I will promptly respond to requests for additional information from the FOCUS™ Program.

Prescriber Signature

Date

Prescriber Information

Prescriber Name, Credentials _____

DEA Registration Number _____ Specialty _____

Affiliation _____

Address _____

City _____ State _____ Zip Code _____

Office Phone _____ Office Fax _____

E-mail _____ Office Manager Name _____

How do you want to be confidentially informed of the results of your knowledge assessment? _____ via e-mail _____ via fax

Please fax this completed prescriber enrollment form (3 pages) to the FOCUS™ Program for ONSOLIS™ at **1-800-558-6302**. For questions regarding the FOCUS™ Program for ONSOLIS™, call **1-877-466-7654 (1-877-4ONSOLIS)**.



Prescriber Name (print): _____

Prescriber Knowledge Assessment

1. When converted to a morphine equivalent dose, what is the minimal daily total dose (mg) of background opioid (also known as around-the-clock or baseline opioid) to render a patient “opioid tolerant”?
 - A. 60 mg
 - B. 15 mg
 - C. 120 mg
2. Contraindications for ONSOLIS™ include:
 - A. treatment of headache or migraine
 - B. treatment of dental pain
 - C. treatment of acute or postoperative pain, or emergency room use
 - D. all of the above
3. The most important reason why ONSOLIS™ should not be given to opioid NON-tolerant patients is because it may cause:
 - A. life-threatening respiratory depression
 - B. nausea
 - C. headache
 - D. constipation
4. If a patient has been using a different transmucosal fentanyl product and the dose is known (such as Actiq® 600 mcg), what is the proper way to determine the dose of ONSOLIS™?
 - A. the ONSOLIS™ dose is the same as other transmucosal fentanyl products
 - B. due to differences in bioavailability, the ONSOLIS™ dose is 2/3 the dose of other transmucosal fentanyl products
 - C. the ONSOLIS™ starting dose is always 200 mcg and the patient should titrate to an effective and tolerable dose of ONSOLIS™ regardless of previous medications

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

The program requires the education of prescribers, pharmacists, patients, and caregivers regarding the safe use of ONSOLIS™.

The FOCUS™ Program for ONSOLIS™ has the following goal:

To mitigate the risk of ONSOLIS™ overdose, abuse, addiction, and serious complications due to medication errors by:

- Helping to assure proper patient selection, including avoidance of the use of ONSOLIS™ in opioid non-tolerant patients;
- Reducing the risk of exposure to ONSOLIS™ in persons for whom it was not prescribed, including accidental exposure in children; and
- Training prescribers, pharmacists, and patients about proper dosing and administration.

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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.

The FOCUS™ Program for ONSOLIS™



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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.

[Important Safety Information >](#)

[PRESCRIBING INFORMATION >](#)

[Privacy Policy >](#)

[MEDA Pharmaceuticals >](#)

MEDA
PHARMACEUTICALS

The FOCUS™ Program for ONSOLIS™



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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.

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.

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 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)].

Information for prescribers

Healthcare Professional Program Overview



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

[Click to open](#)

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

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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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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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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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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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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.

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Dosing & Administration, cont'd

Dose Titration

ONSOLIS™ is available in five dosage strengths:
200, 400, 600, 800, and 1200 mcg

The initial dose is 200 mcg ONSOLIS™

↓ Titrate by incrementally increasing the dose once per episode

Fentanyl dose	200 mcg	400 mcg	600 mcg	800 mcg	1200 mcg
Using	200 mcg ONSOLIS™ film(s)				1200 mcg ONSOLIS™ film
Number of films	1	2	3	4	1



If adequate pain relief is achieved, treat subsequent breakthrough cancer pain episodes using the determined dose.

ONSOLIS™ should only be used once per episode.
ONSOLIS™ dosing should be separated by at least 2 hours.
During any episode, if adequate pain relief is not achieved within 30 minutes, the patient may use a rescue medication as directed.

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Dosing & Administration, cont'd

Dosage adjustment

During maintenance treatment, if the prescribed dose no longer adequately manages the breakthrough cancer pain episode for several consecutive episodes, increase the dose of ONSOLIS™ as described in dose titration (see above). Once a successful dose has been found, each episode is treated with a single film. ONSOLIS™ should be limited to four or fewer doses per day. Consider increasing the dose of the around-the-clock medicine used for persistent cancer pain in patients experiencing more than four breakthrough cancer pain episodes daily.

Administration of ONSOLIS™

- Use the tongue to wet the inside of the cheek or rinse the mouth with water to wet the area for placement of ONSOLIS™.
- Open the ONSOLIS™ package immediately prior to product use.
- Place the entire ONSOLIS™ film near the tip of a dry finger with the pink side facing up.
- Place the pink side of the ONSOLIS™ film against the inside of the cheek.
- Press and hold the ONSOLIS™ film in place for 5 seconds.
- The ONSOLIS™ film should stay in place on its own after this period.

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Dosing & Administration, cont'd

Liquids may be consumed after 5 minutes.

An ONSOLIS™ film, if chewed and/or swallowed, might result in lower peak concentrations and lower bioavailability than when used as directed.

The ONSOLIS™ film should not be cut or torn prior to use.

The ONSOLIS™ film will dissolve within 15 to 30 minutes after application. The film should not be manipulated with the tongue or finger(s) and eating food should be avoided until the film has dissolved.

Drug Interactions

Fentanyl is metabolized mainly via the human cytochrome P450 3A4 (CYP3A4) isoenzyme system; therefore potential drug interactions may occur when ONSOLIS is given concurrently with agents that affect CYP3A4 activity. Concomitant use of ONSOLIS with CYP3A4 inhibitors (e.g., erythromycin, ketoconazole, and certain protease inhibitors) may result in an increase in fentanyl plasma concentrations, and may cause potentially fatal respiratory depression.

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General Opioid Use

The following information was abstracted from: The Use of Opioids for the Treatment of Chronic Pain. A consensus statement from American Academy of Pain Medicine and American Pain Society.

- Addiction is a compulsive disorder in which an individual becomes preoccupied with obtaining and using a substance, the continued use of which results in a decreased quality of life.
- Respiratory depression is a major risk of opioid treatment, particularly in patients who are opioid-naïve.
- Tolerance is decreasing pain relief with the same dosage over time.
- Diversion of opioids can occur and should be watched for.

Principles of good medical practice should guide the prescribing of opioids:

- Proper Evaluation of the patient is essential.
- A thorough Treatment Plan includes multiple modalities, documentation of informed consent of risks and benefits, conditions of use and a written patient agreement.
- An opioid trial should not be done in the absence of a complete assessment of the pain complaint.

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

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General Opioid Use, cont'd

- Consultation with a specialist in pain medicine or with a psychologist may be warranted.
- Review of treatment should occur periodically, including need for continued opioid therapy and indicators of misuse.
- Documentation is essential for supporting the evaluation, the reason for opioid prescribing, the overall pain management treatment plan, any consultations received, and periodic review of the status of the patient.

The following information was abstracted from: Substance Abuse in Brief Fact Sheet. Pain Management Without Psychological Dependence: A Guide for Healthcare Providers.

Assessment of the Risks of Addiction:

- **Obtain relevant patient background information** regarding history of personal or familial problems with alcohol or drugs, legal problems, or misuse of prescription drugs.
- **Use screening instruments** which may include the Opioid Risk Tool, the Pain Medication Questionnaire, the Screener and Opioid Assessment for Patients with Pain (SOAPP), or the Screening Tool for Addiction Risk.

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General Opioid Use, cont'd

- **Document appropriately.** Have patients sign an agreement outlining the risks and benefits of the proposed treatment.
- The possibility of psychological dependence should be considered when a pattern of inappropriate behaviors is observed.

Risks of ONSOLIS™

Overdose

There is a risk of overdose if ONSOLIS™ is given to:

- someone for whom it has not been prescribed; or
- opioid non-tolerant patients.

The manifestations of ONSOLIS™ overdosage are expected to be similar in nature to intravenous fentanyl and other opioids, and are an extension of its pharmacological actions with the most serious significant effect being hypoventilation.

Immediate management of opioid overdose includes removal of the ONSOLIS™ film, if still in the mouth, ensuring a patent airway, physical and verbal stimulation of the patient, and assessment of level of consciousness, ventilatory and circulatory status.

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Risks of ONSOLIS™, cont'd

To treat overdosage (accidental ingestion) in an opioid non-tolerant person, provide ventilatory support, obtain intravenous access, and employ naloxone or other opioid antagonists as clinically indicated. The duration of respiratory depression following overdose may be longer than the effects of the opioid antagonist's action (e.g., the half-life of naloxone ranges from 30 to 81 minutes) and repeated administration may be necessary. Consult the package Insert of the individual opioid antagonist for details about such use.

Management of severe ONSOLIS™ overdose includes: securing a patent airway, assisting or controlling ventilation, establishing intravenous access, and GI decontamination by lavage and/or activated charcoal, once the patient's airway is secure. In the presence of hypoventilation or apnea, assist or control ventilation, and administer oxygen as indicated.

Although muscle rigidity interfering with respiration has not been seen following the use of ONSOLIS™, this is possible with fentanyl and other opioids. If it occurs, manage by the use of assisted or controlled ventilation, by the administration of an opioid antagonist, and as a final alternative, by administration of a neuromuscular blocking agent.

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Risks of ONSOLIS™, cont'd ***Abuse and Addiction***

There is a risk of abuse and addiction from exposure to ONSOLIS™. Fentanyl is a Schedule II controlled substance that can produce drug dependence of the morphine type. ONSOLIS™ may be subject to misuse, abuse and addiction.

Manage the handling of ONSOLIS™ to minimize the risk of abuse, including restriction of access and accounting procedures as appropriate to the clinical setting and as required by law.

Concerns about abuse and addiction should not prevent the proper management of pain. However, all patients treated with opioids require careful monitoring for signs of abuse and addiction, because use of opioid analgesic products carries the risk of addiction even under appropriate medical use.

Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving. Drug addiction is a treatable disease, utilizing a multidisciplinary approach, but relapse is common. "Drug-seeking" behavior is very common in addicts and drug abusers.

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Risks of ONSOLIS™, cont'd

Abuse and addiction are separate and distinct from physical dependence and tolerance. Physicians should be aware that addiction may not be accompanied by concurrent tolerance and symptoms of physical dependence in all addicts. In addition, abuse of opioids can occur in the absence of addiction and is characterized by misuse for nonmedical purposes, often in combination with other psychoactive substances. Since ONSOLIS™ may be abused for nonmedical use, careful record keeping of prescribing information, including quantity, frequency, and renewal requests is strongly advised.

Proper assessment of patients, proper prescribing practices, periodic reevaluation of therapy, and proper dispensing and storage are appropriate measures that help to limit abuse of opioid drugs.

Healthcare professionals should contact their State Professional Licensing Board or State Controlled Substances Authority for information on how to prevent and detect abuse of this product.

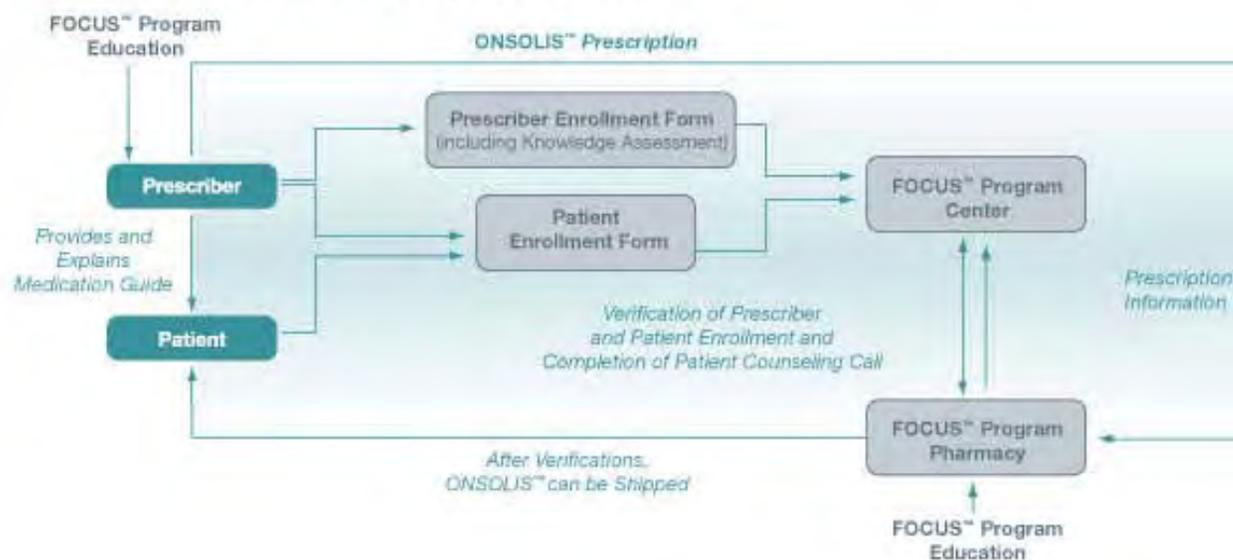
For more information about general opioid use, visit the following websites:

- The Use of Opioids for the Treatment of Chronic Pain. A consensus statement from American Academy of Pain Medicine and American Pain Society (www.ampainsoc.org/advocacy/opioids.htm)
- Substance Abuse in Brief Fact Sheet. Pain Management Without Psychological Dependence: A Guide for Healthcare Providers (www.kap.samhsa.gov/products/brochures/pdfs/saib_0401.pdf)

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Overview of The FOCUS™ Program for ONSOLIS™



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Overview of The FOCUS™ Program for ONSOLIS™, cont'd

The FOCUS™ Program for ONSOLIS™ is designed to provide facilitated, managed distribution with training and enrollment of all stakeholders involved. The purpose of this program is to mitigate the risk of ONSOLIS™ overdose, abuse, addiction, and serious complications due to medication errors. Every prescriber, patient, wholesaler/distributor, and FOCUS™ Program pharmacy is required to enroll in the program. As a result, any stakeholder involved in prescribing, dispensing, or receiving ONSOLIS™ will have been trained on its safe use conditions. This program may also minimize the risk of drug diversion and fraudulent prescriptions.

The key elements of this program are:

- Enrollment of all healthcare providers who will be prescribing ONSOLIS™;
- Enrollment of all patients prior to being prescribed ONSOLIS™; and
- Creation of a dispensing process that utilizes only enrolled pharmacies to assure safe dispensing of ONSOLIS™.

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Overview of The FOCUS™ Program for ONSOLIS™, cont'd

Prescriber Enrollment

Prescriber education and enrollment process is comprised of the following 3 steps that must be completed prior to prescribing ONSOLIS™:

1. The prescriber reviews the educational materials (Website Educational Materials or Printed Educational Materials).
2. The prescriber completes and signs the Prescriber Enrollment Form (including Prescriber Knowledge Assessment) and faxes it to the FOCUS™ Program.
3. A FOCUS™ Program professional reviews the form, requests any missing or illegible information, and, when the necessary forms have been verified to be accurate and complete (including successful completion of the Prescriber Knowledge Assessment), the prescriber is notified of activation.

Prescribers will be re-educated (complete review of all educational materials) and re-enrolled (including Prescriber Knowledge Assessment) following substantial changes to the program or at least every 2 years.

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Overview of The FOCUS™ Program for ONSOLIS™, cont'd

Patient Enrollment

The patient (or legally authorized representative) counseling and enrollment process is comprised of the following 5 steps that must be completed prior to dispensing the patient's first prescription of ONSOLIS™.

1. The prescriber counsels the patient on the Medication Guide for ONSOLIS™
2. The prescriber and patient complete and sign the Patient Enrollment Form and the prescriber faxes it to the FOCUS™ Program.
3. A FOCUS™ Program professional reviews the form and requests any missing or illegible information.
4. The FOCUS™ Program counseling call to the patient is completed.
5. When the previous steps have been successfully completed, the prescriber and pharmacy are notified of patient activation.

Patients will be re-counseled (complete review of the current Medication Guide for ONSOLIS™) and re-enrolled following substantial changes to the program or at least every 2 years. If an active patient transfers to another active prescriber, the patient and new prescriber must complete a new Patient Enrollment Form.

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Overview of The FOCUS™ Program for ONSOLIS™, cont'd

Pharmacy Enrollment

The FOCUS™ Pharmacy education and enrollment process is comprised of the following 3 steps that must be completed prior to receiving ONSOLIS™ inventory for dispensing:

1. The Pharmacist-in-Charge reviews the educational materials (Website Educational Materials or Printed Educational Materials).
2. The Pharmacist-in-Charge completes and signs the Pharmacy Enrollment Form and faxes it to the FOCUS™ Program.
3. A FOCUS™ Program professional reviews the form, requests any missing or illegible information, and, when the form has been verified to be accurate and successfully completed, the pharmacy is notified of activation

FOCUS™ pharmacies will be re-educated (complete review of all educational materials) and re-enrolled following substantial changes to the program or at least every 2 years.

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Overview of The FOCUS™ Program for ONSOLIS™, cont'd

Prescription Processes

Process for Initial Prescription

The first prescription for ONSOLIS™ is processed by the FOCUS™ pharmacy according to the following 2 steps:

1. Prescriber faxes the initial prescription for ONSOLIS™ to the FOCUS™ Program to start the verification process. Prescriber sends the original, hardcopy prescription via a secure, traceable courier to an active FOCUS™ pharmacy. The original, hardcopy prescription must be received by the FOCUS™ pharmacy before dispensing ONSOLIS™.
2. Prior to dispensing, the FOCUS™ pharmacy verifies (via receipt of a unique FOCUS™ Program database authorization number) the following:
 - a. Prescriber is active in the FOCUS™ Program,
 - b. Patient is active in the FOCUS™ Program through the current prescriber, and
 - c. Patient has successfully completed a FOCUS™ Program counseling call to review the safe use conditions and to ensure that their prescriber has performed the following steps prior to dispensing ONSOLIS™:

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Overview of The FOCUS™ Program for ONSOLIS™, cont'd

- i. counseled the patient (or legally authorized representative) that they must be regularly using another opioid pain medicine for their constant pain and their body must be used to this medicine (opioid tolerant),
- ii. counseled the patient (or legally authorized representative) on appropriate product use and contraindications, and
- iii. provided a Medication Guide for ONSOLIS™ to the patient (or legally authorized representative) and reviewed it with them.

Once all of the above conditions are met, ONSOLIS™ can be dispensed by a FOCUS™ pharmacy via a secure, traceable courier (with proof of delivery and adult signature required) to an address specified by the patient.

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Overview of The FOCUS™ Program for ONSOLIS™, cont'd

Process for Subsequent Prescriptions

Subsequent prescriptions for ONSOLIS™ by the same prescriber for the same patient are processed according to the following 2 steps:

1. Prescriber sends the original, hardcopy prescription for ONSOLIS™ via a secure, traceable courier to an active FOCUS™ pharmacy. The original, hardcopy prescription must be received by the FOCUS™ pharmacy before dispensing ONSOLIS™.
2. Prior to dispensing, the FOCUS™ pharmacy verifies (via receipt of a unique FOCUS™ Program database authorization number) the following:
 - a. Prescriber is active in the FOCUS™ Program,
 - b. Patient is active in the FOCUS™ Program through the current prescriber, and
 - c. Patient has previously received a prescription for ONSOLIS™ and successfully completed a FOCUS™ Program counseling call.

Once all of the above conditions are met, ONSOLIS™ can be dispensed by a FOCUS™ pharmacy via a secure, traceable courier (with proof of delivery and adult signature required) to an address specified by the patient.

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Information for prescribers

Risk Evaluation and Mitigation Strategy



Open this file for a better understanding of the goals and elements of the FOCUS™ Program.

[Click to open](#)

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

Information for prescribers

Prescriber Enrollment Form



1. Print this form including the Knowledge Assessment.
2. Complete, sign, and fax it to 1-800-558-6302.

[Click to open](#)

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

Information for prescribers

Medication Guide

You must review the Medication Guide with your patient or a legally authorized representative and provide a copy to them.



[Click to open](#)

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Patient Enrollment Form



[Click to open](#)

To be signed by you and your patient confirming safe use conditions for ONSOLIS™.

1. Print this form.
2. Complete the form with your patient, sign, and fax it to 1-800-558-6302.

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Healthcare Professional Program Overview



This overview will help you understand the elements of the FOCUS™ Program.

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Pharmacist Education and Enrollment

ONSOLIS™ will only be available to a limited number of specialty pharmacies meeting select criteria. If your specialty pharmacy is interested in participating, please contact the FOCUS Program at 1-877-466-7654 (1-877-4ONSOLIS). Before a specialty pharmacy can enroll in The FOCUS™ Program for ONSOLIS™, the Pharmacist-in-Charge must complete the pharmacist education. All pharmacy staff who will process or dispense prescriptions for ONSOLIS™ must review the Information in each of the following sections to complete the 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

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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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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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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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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.

Information for pharmacists

Dosing & Administration, cont'd

Dose Titration

ONSOLIS™ is available in five dosage strengths:
200, 400, 600, 800, and 1200 mcg

The initial dose is 200 mcg ONSOLIS™

↓ Titrate by incrementally increasing the dose once per episode

Fentanyl dose	200 mcg	400 mcg	600 mcg	800 mcg	1200 mcg
Using	200 mcg ONSOLIS™ film(s)				1200 mcg ONSOLIS™ film
Number of films	1	2	3	4	1

↓
If adequate pain relief is achieved, treat subsequent breakthrough cancer pain episodes using the determined dose.

ONSOLIS™ should only be used once per episode.
ONSOLIS™ dosing should be separated by at least 2 hours.
During any episode, if adequate pain relief is not achieved within 30 minutes, the patient may use a rescue medication as directed.

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Dosing & Administration, cont'd

Dosage adjustment

During maintenance treatment, if the prescribed dose no longer adequately manages the breakthrough cancer pain episode for several consecutive episodes, increase the dose of ONSOLIS™ as described in dose titration (see above). Once a successful dose has been found, each episode is treated with a single film. ONSOLIS™ should be limited to four or fewer doses per day. Consider increasing the dose of the around-the-clock medicine used for persistent cancer pain in patients experiencing more than four breakthrough cancer pain episodes daily.

Administration of ONSOLIS™

- Use the tongue to wet the inside of the cheek or rinse the mouth with water to wet the area for placement of ONSOLIS™.
- Open the ONSOLIS™ package immediately prior to product use.
- Place the entire ONSOLIS™ film near the tip of a dry finger with the pink side facing up.
- Place the pink side of the ONSOLIS™ film against the inside of the cheek.
- Press and hold the ONSOLIS™ film in place for 5 seconds.
- The ONSOLIS™ film should stay in place on its own after this period.

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Dosing & Administration, cont'd

Liquids may be consumed after 5 minutes.

An ONSOLIS™ film, if chewed and/or swallowed, might result in lower peak concentrations and lower bioavailability than when used as directed.

The ONSOLIS™ film should not be cut or torn prior to use.

The ONSOLIS™ film will dissolve within 15 to 30 minutes after application. The film should not be manipulated with the tongue or finger(s) and eating food should be avoided until the film has dissolved.

Drug Interactions

Fentanyl is metabolized mainly via the human cytochrome P450 3A4 (CYP3A4) isoenzyme system; therefore potential drug interactions may occur when ONSOLIS is given concurrently with agents that affect CYP3A4 activity. Concomitant use of ONSOLIS with CYP3A4 inhibitors (e.g., erythromycin, ketoconazole, and certain protease inhibitors) may result in an increase in fentanyl plasma concentrations, and may cause potentially fatal respiratory depression.

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General Opioid Use

The following information was abstracted from: The Use of Opioids for the Treatment of Chronic Pain. A consensus statement from American Academy of Pain Medicine and American Pain Society.

- Addiction is a compulsive disorder in which an individual becomes preoccupied with obtaining and using a substance, the continued use of which results in a decreased quality of life.
- Respiratory depression is a major risk of opioid treatment, particularly in patients who are opioid-naïve.
- Tolerance is decreasing pain relief with the same dosage over time.
- Diversion of opioids can occur and should be watched for.

Principles of good medical practice should guide the prescribing of opioids:

- Proper Evaluation of the patient is essential.
- A thorough Treatment Plan includes multiple modalities, documentation of informed consent of risks and benefits, conditions of use and a written patient agreement.
- An opioid trial should not be done in the absence of a complete assessment of the pain complaint.

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General Opioid Use, cont'd

- Consultation with a specialist in pain medicine or with a psychologist may be warranted.
- Review of treatment should occur periodically, including need for continued opioid therapy and indicators of misuse.
- Documentation is essential for supporting the evaluation, the reason for opioid prescribing, the overall pain management treatment plan, any consultations received, and periodic review of the status of the patient.

The following information was abstracted from: Substance Abuse in Brief Fact Sheet. Pain Management Without Psychological Dependence: A Guide for Healthcare Providers.

Assessment of the Risks of Addiction:

- **Obtain relevant patient background information** regarding history of personal or familial problems with alcohol or drugs, legal problems, or misuse of prescription drugs.
- **Use screening instruments** which may include the Opioid Risk Tool, the Pain Medication Questionnaire, the Screener and Opioid Assessment for Patients with Pain (SOAPP), or the Screening Tool for Addiction Risk.

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General Opioid Use, cont'd

- **Document appropriately.** Have patients sign an agreement outlining the risks and benefits of the proposed treatment.
- The possibility of psychological dependence should be considered when a pattern of inappropriate behaviors is observed.

Risks of ONSOLIS™

Overdose

There is a risk of overdose if ONSOLIS™ is given to:

- someone for whom it has not been prescribed; or
- opioid non-tolerant patients.

The manifestations of ONSOLIS™ overdosage are expected to be similar in nature to intravenous fentanyl and other opioids, and are an extension of its pharmacological actions with the most serious significant effect being hypoventilation.

Immediate management of opioid overdose includes removal of the ONSOLIS™ film, if still in the mouth, ensuring a patent airway, physical and verbal stimulation of the patient, and assessment of level of consciousness, ventilatory and circulatory status.

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Risks of ONSOLIS™, cont'd

To treat overdosage (accidental ingestion) in an opioid non-tolerant person, provide ventilatory support, obtain intravenous access, and employ naloxone or other opioid antagonists as clinically indicated. The duration of respiratory depression following overdose may be longer than the effects of the opioid antagonist's action (e.g., the half-life of naloxone ranges from 30 to 81 minutes) and repeated administration may be necessary. Consult the package insert of the individual opioid antagonist for details about such use.

Management of severe ONSOLIS™ overdose includes: securing a patent airway, assisting or controlling ventilation, establishing intravenous access, and GI decontamination by lavage and/or activated charcoal, once the patient's airway is secure. In the presence of hypoventilation or apnea, assist or control ventilation, and administer oxygen as indicated.

Although muscle rigidity interfering with respiration has not been seen following the use of ONSOLIS™, this is possible with fentanyl and other opioids. If it occurs, manage by the use of assisted or controlled ventilation, by the administration of an opioid antagonist, and as a final alternative, by administration of a neuromuscular blocking agent.

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Risks of ONSOLIS™, cont'd

Abuse and Addiction

There is a risk of abuse and addiction from exposure to ONSOLIS™. Fentanyl is a Schedule II controlled substance that can produce drug dependence of the morphine type. ONSOLIS™ may be subject to misuse, abuse and addiction.

Manage the handling of ONSOLIS™ to minimize the risk of abuse, including restriction of access and accounting procedures as appropriate to the clinical setting and as required by law.

Concerns about abuse and addiction should not prevent the proper management of pain. However, all patients treated with opioids require careful monitoring for signs of abuse and addiction, because use of opioid analgesic products carries the risk of addiction even under appropriate medical use.

Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving. Drug addiction is a treatable disease, utilizing a multidisciplinary approach, but relapse is common. "Drug-seeking" behavior is very common in addicts and drug abusers.

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Risks of ONSOLIS™, cont'd

Abuse and addiction are separate and distinct from physical dependence and tolerance. Physicians should be aware that addiction may not be accompanied by concurrent tolerance and symptoms of physical dependence in all addicts. In addition, abuse of opioids can occur in the absence of addiction and is characterized by misuse for nonmedical purposes, often in combination with other psychoactive substances. Since ONSOLIS™ may be abused for nonmedical use, careful record keeping of prescribing information, including quantity, frequency, and renewal requests is strongly advised.

Proper assessment of patients, proper prescribing practices, periodic reevaluation of therapy, and proper dispensing and storage are appropriate measures that help to limit abuse of opioid drugs.

Healthcare professionals should contact their State Professional Licensing Board or State Controlled Substances Authority for information on how to prevent and detect abuse of this product.

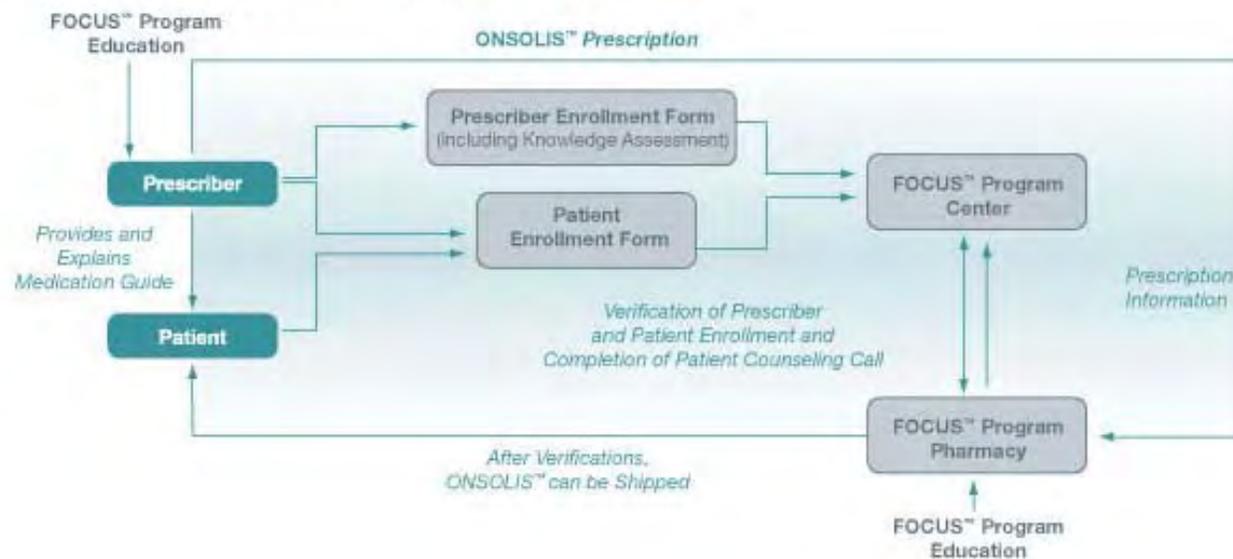
For more information about general opioid use, visit the following websites:

- The Use of Opioids for the Treatment of Chronic Pain. A consensus statement from American Academy of Pain Medicine and American Pain Society (www.ampainsoc.org/advocacy/opioids.htm)
- Substance Abuse in Brief Fact Sheet. Pain Management Without Psychological Dependence: A Guide for Healthcare Providers (www.kap.samhsa.gov/products/brochures/pdfs/salb_0401.pdf)

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

Information for pharmacists

Overview of The FOCUS™ Program for ONSOLIS™



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The FOCUS™ Program for ONSOLIS™ is designed to provide facilitated, managed distribution with training and enrollment of all stakeholders involved. The purpose of this program is to mitigate the risk of ONSOLIS™ overdose, abuse, addiction, and serious complications due to medication errors. Every prescriber, patient, wholesaler/distributor, and FOCUS™ Program pharmacy is required to enroll in the program. As a result, any stakeholder involved in prescribing, dispensing, or receiving ONSOLIS™ will have been trained on its safe use conditions. This program may also minimize the risk of drug diversion and fraudulent prescriptions.

The key elements of this program are:

- Enrollment of all healthcare providers who will be prescribing ONSOLIS™;
- Enrollment of all patients prior to being prescribed ONSOLIS™; and
- Creation of a dispensing process that utilizes only enrolled pharmacies to assure safe dispensing of ONSOLIS™.

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Overview of The FOCUS™ Program for ONSOLIS™, cont'd

Prescriber Enrollment

Prescriber education and enrollment process is comprised of the following 3 steps that must be completed prior to prescribing ONSOLIS™:

1. The prescriber reviews the educational materials (Website Educational Materials or Printed Educational Materials).
2. The prescriber completes and signs the Prescriber Enrollment Form (including Prescriber Knowledge Assessment) and faxes it to the FOCUS™ Program.
3. A FOCUS™ Program professional reviews the form, requests any missing or illegible information, and, when the necessary forms have been verified to be accurate and complete (including successful completion of the Prescriber Knowledge Assessment), the prescriber is notified of activation.

Prescribers will be re-educated (complete review of all educational materials) and re-enrolled (including Prescriber Knowledge Assessment) following substantial changes to the program or at least every 2 years.

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Patient Enrollment

The patient (or legally authorized representative) counseling and enrollment process is comprised of the following 5 steps that must be completed prior to dispensing the patient's first prescription of ONSOLIS™.

1. The prescriber counsels the patient on the Medication Guide for ONSOLIS™
2. The prescriber and patient complete and sign the Patient Enrollment Form and the prescriber faxes it to the FOCUS™ Program.
3. A FOCUS™ Program professional reviews the form and requests any missing or illegible information.
4. The FOCUS™ Program counseling call to the patient is completed.
5. When the previous steps have been successfully completed, the prescriber and pharmacy are notified of patient activation.

Patients will be re-counseled (complete review of the current Medication Guide for ONSOLIS™) and re-enrolled following substantial changes to the program or at least every 2 years. If an active patient transfers to another active prescriber, the patient and new prescriber must complete a new Patient Enrollment Form.

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Pharmacy Enrollment

The FOCUS™ Pharmacy education and enrollment process is comprised of the following 3 steps that must be completed prior to receiving ONSOLIS™ inventory for dispensing:

1. The Pharmacist-In-Charge reviews the educational materials (Website Educational Materials or Printed Educational Materials).
2. The Pharmacist-In-Charge completes and signs the Pharmacy Enrollment Form and faxes it to the FOCUS™ Program.
3. A FOCUS™ Program professional reviews the form, requests any missing or illegible information, and, when the form has been verified to be accurate and successfully completed, the pharmacy is notified of activation

FOCUS™ pharmacies will be re-educated (complete review of all educational materials) and re-enrolled following substantial changes to the program or at least every 2 years.

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Prescription Processes

Process for Initial Prescription

The first prescription for ONSOLIS™ is processed by the FOCUS™ pharmacy according to the following 2 steps:

1. Prescriber faxes the initial prescription for ONSOLIS™ to the FOCUS™ Program to start the verification process. Prescriber sends the original, hardcopy prescription via a secure, traceable courier to an active FOCUS™ pharmacy. The original, hardcopy prescription must be received by the FOCUS™ pharmacy before dispensing ONSOLIS™.
2. Prior to dispensing, the FOCUS™ pharmacy verifies (via receipt of a unique FOCUS™ Program database authorization number) the following:
 - a. Prescriber is active in the FOCUS™ Program,
 - b. Patient is active in the FOCUS™ Program through the current prescriber, and
 - c. Patient has successfully completed a FOCUS™ Program counseling call to review the safe use conditions and to ensure that their prescriber has performed the following steps prior to dispensing ONSOLIS™:

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- i. counseled the patient (or legally authorized representative) that they must be regularly using another opioid pain medicine for their constant pain and their body must be used to this medicine (opioid tolerant),
- ii. counseled the patient (or legally authorized representative) on appropriate product use and contraindications, and
- iii. provided a Medication Guide for ONSOLIS™ to the patient (or legally authorized representative) and reviewed it with them.

Once all of the above conditions are met, ONSOLIS™ can be dispensed by a FOCUS™ pharmacy via a secure, traceable courier (with proof of delivery and adult signature required) to an address specified by the patient.

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Process for Subsequent Prescriptions

Subsequent prescriptions for ONSOLIS™ by the same prescriber for the same patient are processed according to the following 2 steps:

1. Prescriber sends the original, hardcopy prescription for ONSOLIS™ via a secure, traceable courier to an active FOCUS™ pharmacy. The original, hardcopy prescription must be received by the FOCUS™ pharmacy before dispensing ONSOLIS™.
2. Prior to dispensing, the FOCUS™ pharmacy verifies (via receipt of a unique FOCUS™ Program database authorization number) the following:
 - a. Prescriber is active in the FOCUS™ Program,
 - b. Patient is active in the FOCUS™ Program through the current prescriber, and
 - c. Patient has previously received a prescription for ONSOLIS™ and successfully completed a FOCUS™ Program counseling call.

Once all of the above conditions are met, ONSOLIS™ can be dispensed by a FOCUS™ pharmacy via a secure, traceable courier (with proof of delivery and adult signature required) to an address specified by the patient.

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Risk Evaluation and Mitigation Strategy



Open this file for a better understanding of the goals and elements of the FOCUS™ Program.

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This overview will help you understand the elements of the FOCUS™ Program for patients.

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To help you better respond to questions patients may ask about ONSOLIS™ and ensure that a Medication Guide for ONSOLIS™ is provided to every patient each time a prescription is dispensed.

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Click to open

This overview will help you understand what you must do in order to receive ONSOLIS™.

If you think that ONSOLIS™ might be right for you, please contact your healthcare provider.

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

The FOCUS™ Program for ONSOLIS™

Educational Materials for Prescribers and Pharmacists

The FOCUS™ Program for ONSOLIS™

The program requires the education of prescribers, pharmacists, patients, and caregivers regarding the safe use of ONSOLIS™. For information on the FOCUS™ Program call 1-877-466-7654 (1-877-4ONSOLIS) or visit www.OnsolisFocus.com.

The FOCUS™ Program for ONSOLIS™ has the following goal:

To mitigate the risk of ONSOLIS™ overdose, abuse, addiction, and serious complications due to medication errors by:

- Helping to assure proper patient selection, including avoidance of the use of ONSOLIS™ in opioid non-tolerant patients;
- Reducing the risk of exposure to ONSOLIS™ in persons for whom it was not prescribed, including accidental exposure in children; and
- Training prescribers, pharmacists, and patients about proper dosing and administration.

The 3-Step FOCUS™ Program Process

1. Complete Prescriber Education, Assessment, and Enrollment

- Review the educational materials on proper use of ONSOLIS™
- Complete the Prescriber Knowledge Assessment; sign and fax the Prescriber Enrollment Form
Satisfactory completion of the Prescriber Knowledge Assessment is required

2. Complete Patient Counseling and Enrollment

- Determine that the patient meets the necessary requirements and is an appropriate candidate for treatment with ONSOLIS™
- Counsel the patient (or legally authorized representative) about the benefits and risks, and review the Medication Guide for ONSOLIS™
- Provide the patient with the Patient Authorization for Disclosure and Use of Health Information Statement (HIPAA)
- Complete and fax a copy of the Patient Enrollment Form

3. Initiate Delivery Process

- Fax a copy of the initial prescription for ONSOLIS to expedite the dispensing process
- Send the original, hardcopy prescription for ONSOLIS via courier using the supplied, pre-paid shipping label/airbill to initiate secure delivery of ONSOLIS™ directly to the patient or their caregiver

For further information please contact the FOCUS™ Program for ONSOLIS™ directly at 1-877-466-7654 (1-877-4ONSOLIS), or visit www.OnsolisFocus.com

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 oral 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.

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.

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 microgram per microgram basis from any other oral transmucosal fentanyl product to ONSOLIS™** as ONSOLIS™ is not equivalent on a microgram per microgram 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** of the 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 ONSOLIS™, should dispose of all remaining unused 200 mcg ONSOLIS™ films. The patient should then get a prescription for ONSOLIS™ films of the identified dose strength (ie, 200, 400, 600, 800, or 1200 mcg) to treat subsequent episodes.

Dosing & Administration (cont'd)

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.

Dose Titration

ONSOLIS is available in five dosage strengths:
200, 400, 600, 800, and 1200 mcg

The initial dose is 200 mcg ONSOLIS

Titrate by incrementally increasing the dose once per episode

Fentanyl dose	200 mcg	400 mcg	600 mcg	800 mcg	1200 mcg
Using	200 mcg ONSOLIS film(s)				1200 mcg ONSOLIS film
Number of films	1	2	3	4	1

If adequate pain relief *is achieved*, treat subsequent breakthrough cancer pain episodes using the determined dose.

**ONSOLIS should only be used once per episode.
ONSOLIS dosing should be separated by at least 2 hours.**

During any episode, if adequate pain relief *is not achieved* within 30 minutes, the patient may use a rescue medication as directed.

Dosage adjustment

During maintenance treatment, if the prescribed dose no longer adequately manages the breakthrough cancer pain episode for several consecutive episodes, increase the dose of ONSOLIS™ as described in dose titration (see above). Once a successful dose has been found, each episode is treated with a single film. ONSOLIS™ should be limited to four or fewer doses per day. Consider increasing the dose of the around-the-clock opioid medicine used for persistent cancer pain in patients experiencing more than four breakthrough cancer pain episodes daily.

Administration of ONSOLIS™

- Use the tongue to wet the inside of the cheek or rinse the mouth with water to wet the area for placement of ONSOLIS™.
- Open the ONSOLIS™ package immediately prior to product use.
- Place the entire ONSOLIS™ film near the tip of a dry finger with the pink side facing up.
- Place the pink side of the ONSOLIS™ film against the inside of the cheek.
- Press and hold the ONSOLIS™ film in place for 5 seconds.
- The ONSOLIS™ film should stay in place on its own after this period.

Liquids may be consumed after 5 minutes.

An ONSOLIS™ film, if chewed and/or swallowed, might result in lower peak concentrations and lower bioavailability than when used as directed.

The ONSOLIS™ film should not be cut or torn prior to use.

The ONSOLIS™ film will dissolve within 15 to 30 minutes after application. The film should not be manipulated with the tongue or finger(s) and eating food should be avoided until the film has dissolved.

Drug interactions

Fentanyl is metabolized mainly via the human cytochrome P450 3A4 (CYP3A4) isoenzyme system; therefore potential drug interactions may occur when ONSOLIS™ is given concurrently with agents that affect CYP3A4 activity. Concomitant use of ONSOLIS™ with CYP3A4 inhibitors (e.g., erythromycin, ketoconazole, and certain protease inhibitors) may result in an increase in fentanyl plasma concentrations, and may cause potentially fatal respiratory depression.

General Opioid Use

The following information was abstracted from: The Use of Opioids for the Treatment of Chronic Pain. A consensus statement from American Academy of Pain Medicine and American Pain Society.

- Addiction is a compulsive disorder in which an individual becomes preoccupied with obtaining and using a substance, the continued use of which results in a decreased quality of life.
- Respiratory depression is a major risk of opioid treatment, particularly in patients who are opioid-naïve.
- Tolerance is decreasing pain relief with the same dosage over time.
- Diversion of opioids can occur and should be watched for.

Principles of good medical practice should guide the prescribing of opioids:

- Proper Evaluation of the patient is essential.
- A thorough Treatment Plan includes multiple modalities, documentation of informed consent of risks and benefits, conditions of use and a written patient agreement.
- An opioid trial should not be done in the absence of a complete assessment of the pain complaint.
- Consultation with a specialist in pain medicine or with a psychologist may be warranted.
- Review of treatment should occur periodically, including need for continued opioid therapy and indicators of misuse.
- Documentation is essential for supporting the evaluation, the reason for opioid prescribing, the overall pain management treatment plan, any consultations received, and periodic review of the status of the patient.

The following information was abstracted from: Substance Abuse in Brief Fact Sheet. Pain Management Without Psychological Dependence: A Guide for Healthcare Providers.

Assessment of the Risks of Addiction:

- **Obtain relevant patient background information** regarding history of personal or familial problems with alcohol or drugs, legal problems, or misuse of prescription drugs.
- **Use screening instruments** which may include the Opioid Risk Tool, the Pain Medication Questionnaire, the Screener and Opioid Assessment for Patients with Pain (SOAPP), or the Screening Tool for Addiction Risk.
- **Document appropriately.** Have patients sign an agreement outlining the risks and benefits of the proposed treatment.
- The possibility of psychological dependence should be considered when a pattern of inappropriate behaviors is observed.

Risks of ONSOLIS™

Overdose

There is a high risk of overdose if ONSOLIS™ is given to:

- someone for whom it has not been prescribed; or
- opioid non-tolerant patients.

The manifestations of ONSOLIS™ overdosage are expected to be similar in nature to intravenous fentanyl and other opioids, and are an extension of its pharmacological actions with the most serious significant effect being hypoventilation.

Immediate management of opioid overdose includes removal of the ONSOLIS film, if still in the mouth, ensuring a patent airway, physical and verbal stimulation of the patient, and assessment of level of consciousness, ventilatory and circulatory status.

To treat overdosage (accidental ingestion) in an opioid non-tolerant person, provide ventilatory support, obtain intravenous access, and employ naloxone or other opioid antagonists as clinically indicated. The duration of respiratory depression following overdose may be longer than the effects of the opioid antagonist's action (e.g., the half-life of naloxone ranges from 30 to 81 minutes) and repeated administration may be necessary. Consult the package insert of the individual opioid antagonist for details about such use.

Management of severe ONSOLIS™ overdose includes: securing a patent airway, assisting or controlling ventilation, establishing intravenous access, and GI decontamination by lavage and/or activated charcoal, once the patient's airway is secure. In the presence of hypoventilation or apnea, assist or control ventilation, and administer oxygen as indicated.

Although muscle rigidity interfering with respiration has not been seen following the use of ONSOLIS™, this is possible with fentanyl and other opioids. If it occurs, manage by the use of assisted or controlled ventilation, by the administration of an opioid antagonist, and as a final alternative, by administration of a neuromuscular blocking agent.

Abuse and Addiction

There is a risk of abuse and addiction from exposure to ONSOLIS™. Fentanyl is a Schedule II controlled substance that can produce drug dependence of the morphine type. ONSOLIS™ may be subject to misuse, abuse and addiction.

Manage the handling of ONSOLIS™ to minimize the risk of abuse, including restriction of access and accounting procedures as appropriate to the clinical setting and as required by law.

Concerns about abuse and addiction should not prevent the proper management of pain. However, all patients treated with opioids require careful monitoring for signs of abuse and addiction, because use of opioid analgesic products carries the risk of addiction even under appropriate medical use.

Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving. Drug addiction is a treatable disease, utilizing a multidisciplinary approach, but relapse is common. "Drug-seeking" behavior is very common in addicts and drug abusers.

Risks of ONSOLIS™ (cont'd)

Abuse and addiction are separate and distinct from physical dependence and tolerance. Physicians should be aware that addiction may not be accompanied by concurrent tolerance and symptoms of physical dependence in all addicts. In addition, abuse of opioids can occur in the absence of addiction and is characterized by misuse for nonmedical purposes, often in combination with other psychoactive substances. Since ONSOLIS™ may be abused for nonmedical use; careful record keeping of prescribing information, including quantity, frequency, and renewal requests is strongly advised.

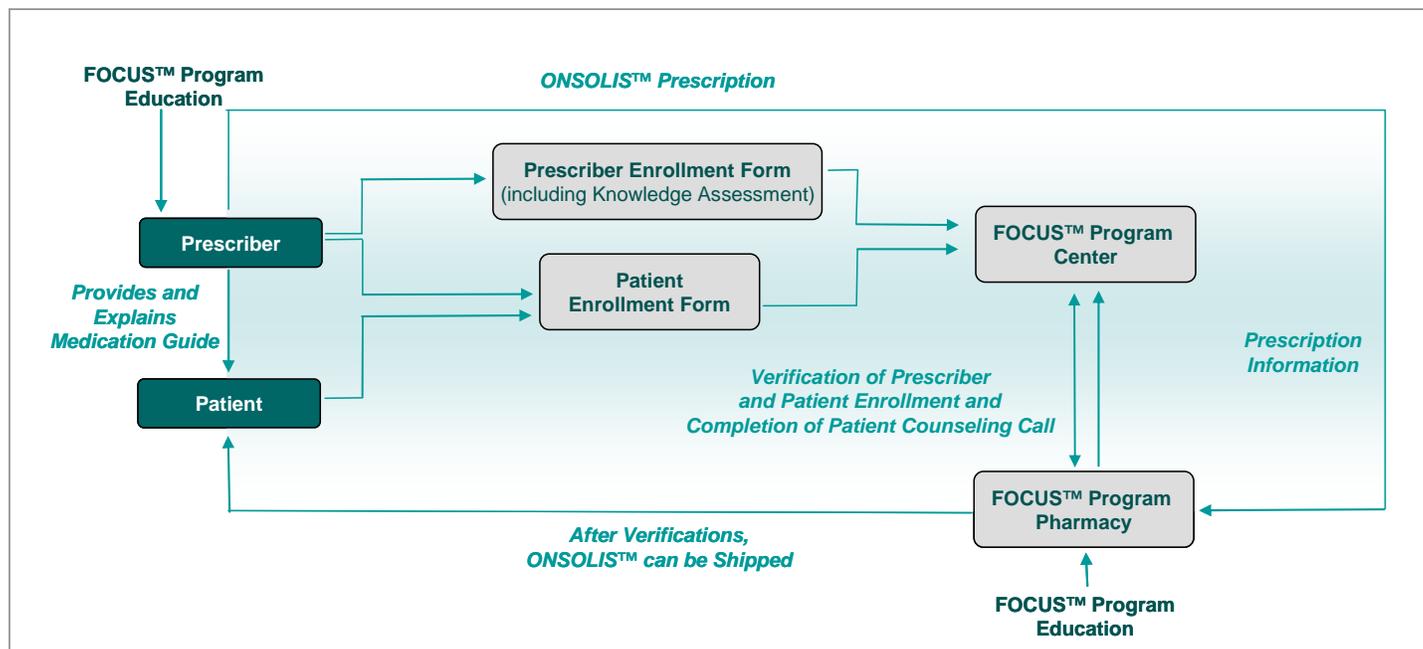
Proper assessment of patients, proper prescribing practices, periodic reevaluation of therapy, and proper dispensing and storage are appropriate measures that help to limit abuse of opioid drugs.

Healthcare professionals should contact their State Professional Licensing board or State Controlled Substances Authority for information on how to prevent and detect abuse of this product.

For more information about general opioid use, visit the following websites:

- [The Use of Opioids for the Treatment of Chronic Pain. A consensus statement from American Academy of Pain Medicine and American Pain Society \(www.ampainsoc.org/advocacy/opioids.htm\)](http://www.ampainsoc.org/advocacy/opioids.htm)
- [Substance Abuse in Brief Fact Sheet. Pain Management Without Psychological Dependence: A Guide for Healthcare Providers \(www.kap.samhsa.gov/products/brochures/pdfs/saib_0401.pdf\)](http://www.kap.samhsa.gov/products/brochures/pdfs/saib_0401.pdf)

Overview of the FOCUS™ Program for ONSOLIS™



The FOCUS™ Program for ONSOLIS™ is designed to provide facilitated, managed distribution with training and enrollment of all stakeholders involved. The purpose of this program is to mitigate the risk of ONSOLIS™ overdose, abuse, addiction, and serious complications due to medication errors. Every prescriber, patient, wholesaler/distributor, and FOCUS™ Program pharmacy is required to enroll in the program. As a result, any stakeholder involved in prescribing, dispensing, or receiving ONSOLIS™ will have been trained on its safe use conditions. This program may also minimize the risk of drug diversion and fraudulent prescriptions.

The key elements of program are:

- Enrollment of all healthcare providers who will be prescribing ONSOLIS™;
- Enrollment of all patients prior to being prescribed ONSOLIS™; and
- Creation of a dispensing process that utilizes only enrolled pharmacies to help assure safe dispensing of ONSOLIS™.

Overview of the FOCUS™ Program for ONSOLIS™ (cont'd)

Prescriber Enrollment

The prescriber education and enrollment process is comprised of the following 3 steps that must be completed prior to prescribing ONSOLIS™:

1. The prescriber reviews the educational materials (Website Educational Materials or Printed Educational Materials).
2. The prescriber completes and signs the Prescriber Enrollment Form (including Prescriber Knowledge Assessment) and faxes it to the FOCUS™ Program.
3. A FOCUS Program professional reviews the form, requests any missing or illegible information, and, when the necessary forms have been verified to be accurate and complete (including successful completion of the Prescriber Knowledge Assessment), the prescriber is notified of activation.

Prescribers will be re-educated (complete review of all educational materials) and re-enrolled (including Prescriber Knowledge Assessment) following substantial changes to the program or at least every 2 years.

Patient Enrollment

The patient (or legally authorized representative) counseling and enrollment process is comprised of the following 5 steps that must be completed prior to dispensing the patient's first prescription of ONSOLIS™:

1. The prescriber counsels the patient on the Medication Guide for ONSOLIS™
2. The prescriber and patient complete and sign the Patient Enrollment Form and the prescriber faxes it to the FOCUS™ Program.
3. A FOCUS Program professional reviews the form and requests any missing or illegible information.
4. The FOCUS Program counseling call to the patient is completed.
5. When the previous steps have been successfully completed, the prescriber and pharmacy are notified of patient activation.

Patients will be re-counseled (complete review of the current Medication Guide for ONSOLIS™) and re-enrolled following substantial changes to the program or at least every 2 years. If an active patient transfers to another active prescriber, the patient and new prescriber must complete a new Patient Enrollment Form.

Pharmacy Enrollment

The FOCUS™ pharmacy education and enrollment process is comprised of the following 3 steps that must be completed prior to receiving ONSOLIS™ inventory for dispensing:

1. The Pharmacist-in-Charge reviews the educational materials (Website Educational Materials or Printed Educational Materials).
2. The Pharmacist-in-Charge completes and signs the Pharmacy Enrollment Form and faxes it to the FOCUS™ Program.
3. A FOCUS Program professional reviews the form, requests any missing or illegible information, and, when the form has been verified to be accurate and successfully completed, the pharmacy is notified of activation.

FOCUS™ pharmacies will be re-educated (complete review of all educational materials) and re-enrolled following substantial changes to the program or at least every 2 years.

Overview of the FOCUS™ Program for ONSOLIS™ (cont'd)

Prescription Processes

Process for Initial Prescription

The first prescription for ONSOLIS™ is processed by the FOCUS pharmacy according to the following 2 steps:

1. Prescriber faxes the initial prescription for ONSOLIS™ to the FOCUS™ Program to start the verification process. Prescriber sends the original, hardcopy prescription via a secure, traceable courier to an active FOCUS pharmacy. The original, hardcopy prescription must be received by the FOCUS pharmacy before dispensing ONSOLIS™.
2. Prior to dispensing, the FOCUS™ pharmacy verifies (via receipt of a unique FOCUS™ Program database authorization number) the following:
 - a. Prescriber is active in the FOCUS™ Program,
 - b. Patient is active in the FOCUS™ Program through the current prescriber, and
 - c. Patient has successfully completed a FOCUS™ Program counseling call to review the safe use conditions and to ensure that their prescriber has performed the following steps prior to dispensing ONSOLIS™:
 - i. counseled the patient (or legally authorized representative) that they must be regularly using another opioid pain medicine for their constant pain and their body must be used to this medicine (opioid tolerant),
 - ii. counseled the patient (or legally authorized representative) on appropriate product use and contraindications, and
 - iii. provided a Medication Guide for ONSOLIS™ to the patient (or legally authorized representative) and reviewed it with them.

Once all of the above conditions are met, ONSOLIS™ can be dispensed by a FOCUS™ pharmacy via a secure, traceable courier (with proof of delivery and adult signature required) to an address specified by the patient.

Process for Subsequent Prescriptions

Subsequent prescriptions for ONSOLIS™ by the same prescriber for the same patient are processed according to the following 2 steps:

1. Prescriber sends the original, hardcopy prescription for ONSOLIS™ via a secure, traceable courier to an active FOCUS™ pharmacy. The original, hardcopy prescription must be received by the FOCUS pharmacy before dispensing ONSOLIS™.
2. Prior to dispensing, the FOCUS™ pharmacy verifies (via receipt of a unique FOCUS™ Program database authorization number) the following:
 - a. Prescriber is active in the FOCUS™ Program,
 - b. Patient is active in the FOCUS™ Program through the current prescriber, and
 - c. Patient has previously received a prescription for ONSOLIS™ and successfully completed a FOCUS™ Program counseling call.

Once all of the above conditions are met, ONSOLIS™ can be dispensed by a FOCUS™ pharmacy via a secure, traceable courier (with proof of delivery and adult signature required) to an address specified by the patient.

Pharmacy Enrollment Form

The FOCUS™ Program for ONSOLIS™



I understand that ONSOLIS™ is available only through the FOCUS™ Program, I agree to comply with the program requirements, and acknowledge that:

1. I will ensure and document that all pharmacy staff who will process or dispense prescriptions for ONSOLIS™ are trained about the FOCUS™ Program for ONSOLIS™ procedures and educational materials. This training documentation is subject to audit.
2. I will ensure that pharmacy staff dispense ONSOLIS™ only after confirming (via FOCUS™ Program database authorization) that patients have met the following safe use conditions:
 - a. Patients have been enrolled in the program, based on a valid prescription from an active prescriber;
 - b. Patients or legally authorized representatives have been counseled regarding the importance of being on an around-the-clock opioid regimen for an adequate amount of time to ensure that they are opioid tolerant. Patients considered opioid tolerant are those who are regularly 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 oxymorphone/day, or an equianalgesic dose of another opioid for one week or longer; and
 - c. Patients or legally authorized representatives have been counseled on appropriate ONSOLIS™ product use.
3. I will ensure that pharmacy staff provide a Medication Guide for ONSOLIS™ to every patient each time a prescription is dispensed.
4. I will ensure that pharmacy staff will not substitute ONSOLIS™ for any other oral transmucosal fentanyl citrate product.
5. I will provide reports of ONSOLIS™ prescription activity to the FOCUS™ Program for ONSOLIS™.
6. I will permit a program-related audit of my pharmacy to establish that ONSOLIS™ is dispensed only after documenting the above safe use conditions.

Pharmacist-in-Charge Signature

Date

Print Name

Title

Pharmacy Information

Pharmacy Name _____

Pharmacist Name _____ DEA Registration Number _____

Address _____

City _____ State _____ Zip Code _____

Office Phone _____ Office Fax _____

Pharmacy Contact _____ Phone _____

Fax _____ E-mail _____

Please fax this completed form to the FOCUS™ Program for ONSOLIS™ at 1-800-558-6302.

For questions regarding the FOCUS™ Program for ONSOLIS™, call 1-877-466-7654 (1-877-4ONSOLIS).

For more information about ONSOLIS™, please see Full Prescribing Information, including BOXED WARNINGS.





Important Prescribing Information About ONSOLIS™ (fentanyl buccal soluble film).

Dear Pharmacist:

MEDA Pharmaceuticals Inc. is introducing ONSOLIS™, a new treatment indicated only for breakthrough pain in patients with cancer, 18 years of age and older. ONSOLIS™ can only be used in patients 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.

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 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 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.

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.

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.

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.

The concomitant use of ONSOLIS™ with CYP3A4 inhibitors may result in an increase in fentanyl plasma concentrations and may cause potentially fatal respiratory depression.

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.

The FOCUS™ Program has been implemented to mitigate the risk of ONSOLIS™ overdose, abuse, addiction, and serious complications due to medication errors by: helping to assure proper patient selection, including avoidance of the use of ONSOLIS™ in opioid non-tolerant patients; reducing the risk of exposure to ONSOLIS™ in persons for whom it was not prescribed, including accidental exposure in children; and training prescribers, pharmacists, and patients about proper dosing and administration. Enrolled patients receive ONSOLIS™ directly from a specialty pharmacy, which delivers the medication via a secure, traceable courier.

Adverse Reactions

The adverse reactions seen with ONSOLIS™ are typical opioid side effects in a population with cancer. Frequently, opioid-associated adverse reactions will cease or decrease in intensity with continued use of ONSOLIS™. **Expect opioid side effects and manage them accordingly.** The most serious adverse reactions associated with all opioids including ONSOLIS™ are respiratory depression (potentially leading to apnea or respiratory arrest), circulatory depression, hypotension, and shock. Follow all patients for symptoms of respiratory depression.

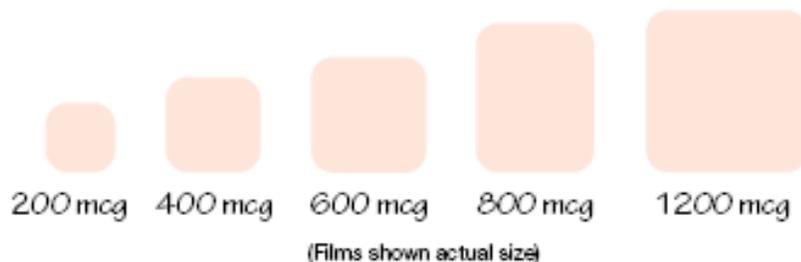
The most common adverse reactions are: nausea, vomiting, dizziness, anemia, dehydration, peripheral edema, dyspnea, and somnolence.

We appreciate your time and consideration and look forward to offering you and your patients continued support.

Sincerely,

[signature]

[name, title, MEDA Pharmaceuticals Inc.]



Please see accompanying Full Prescribing Information, including BOXED WARNINGS.

Patient Program Overview

The FOCUS™ Program for ONSOLIS™



The FOCUS™ Program for ONSOLIS™

The program requires the education of prescribers, pharmacists, patients, and caregivers regarding the safe use of ONSOLIS™.

Your doctor has determined that ONSOLIS™ may help control your pain. Before you can receive ONSOLIS™, you or your legally authorized representative must enroll in the FOCUS™ Program and agree to all program requirements.

The FOCUS™ Program includes the following:

- Your healthcare provider will review the Medication Guide for ONSOLIS™ with you and provide you a copy
- Together, you and your healthcare provider will **complete the Patient Enrollment Form**
- Your healthcare provider will send your enrollment form and prescription for ONSOLIS™ to the FOCUS™ Program
- A FOCUS™ Program professional will contact you (or your legally authorized representative, if applicable) by telephone to provide additional counseling.

(This call must be completed before you can receive ONSOLIS™ for the first time.) Please provide us with a telephone number where you (or your legally authorized representative, if applicable) can be reached and tell us the best time to reach you.

- The FOCUS™ pharmacy will confirm your shipping address and schedule a delivery time.

For questions, visit www.OnsolisFocus.com or contact us directly at **1-877-466-7654 (1-877-4ONSOLIS)**

Patient Enrollment Form

The FOCUS™ Program for ONSOLIS™



As the prescriber of ONSOLIS™, I acknowledge that:

1. This patient being prescribed ONSOLIS™ is opioid tolerant: patients considered opioid tolerant are those who are regularly 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.
2. This patient has been using around-the-clock opioid analgesia for at least 1 week.
3. This patient or a legally authorized representative has been counseled about the risks and benefits and appropriate use of ONSOLIS™, and about the risks of overdose due to giving ONSOLIS™ to someone for whom it has not been prescribed as described in the Medication Guide for ONSOLIS™.
4. I have provided and reviewed the Medication Guide for ONSOLIS™ with this patient or a legally authorized representative.

Prescriber Signature

Date

Prescriber Name, Credentials

DEA Registration Number

Prescriber Fax Number

As the patient being prescribed ONSOLIS™ or a legally authorized representative, I acknowledge that:

1. My prescriber gave me a copy of the Medication Guide for ONSOLIS™ and reviewed it with me. I have asked my prescriber all the questions I have about ONSOLIS™. I will ask my prescriber if I have any additional questions in the future about the use of ONSOLIS™.
2. I understand that there can be serious risks, especially if I do not take ONSOLIS™ as directed.
3. I understand that I must be regularly using another opioid ("narcotic") pain medicine for my constant pain. This is important because my body must become used to opioid medicine before I can take ONSOLIS™ (I am "opioid tolerant").
4. I agree that I will never give ONSOLIS™ to anyone else, even if they have the same symptoms, since it may harm them or even cause death.
5. I will store ONSOLIS™ in a safe place away from children because accidental use by a child is a medical emergency and can result in death.
6. I have reviewed the Patient Authorization for Disclosure and Use of Health Information Statement and I agree to its terms and conditions to authorize my healthcare providers and health plans to disclose my personal and medical information to BioDelivery Sciences International, Inc. (sponsor) / MEDA Pharmaceuticals Inc. (licensee) and their agents and contractors.

Patient Signature/Date

Personal Representative Signature/Date

- Spouse Legal Guardian
 Designated Representative per
Power of Attorney

Personal Representative Name (Printed)

Patient Name (Last)

(First)

□□ / □□
Birthday
(Month and day)

Zip code (5 digits)

Telephone number where you or your legally authorized representative can be reached

Time of day to call: Morning Afternoon Evening

Fax a completed, signed copy of this enrollment form to the FOCUS™ Program for ONSOLIS™ at 1-800-558-6302.

For more information about ONSOLIS™, please see Full Prescribing Information, including BOXED WARNINGS.



Patient Enrollment Form

The FOCUS™ Program for ONSOLIS™



Patient Authorization for Disclosure and Use of Health Information Statement

The FOCUS™ Program for ONSOLIS™

By my signature on the ONSOLIS™ Patient Enrollment Form, I thereby authorize each of my physicians, pharmacists, and other healthcare providers (my "Providers") and each of my health insurers (my "Insurers") to disclose my personally identifiable health information, including my medical diagnosis, condition, and treatment (including prescription information), my health insurance, and my name, address, and telephone number (my "Health Information") to BioDelivery Sciences International, Inc. (BDSI; sponsor)/MEDA Pharmaceuticals Inc. (Meda; licensee), their agents and representatives, including third parties authorized by BDSI/Meda to administer the FOCUS™ Program for the following purposes:

1. Enroll me in the FOCUS™ Program, administer my participation in the program (including contacting me), evaluate the safety of ONSOLIS™ and the effectiveness of the program, provide me with educational information on the FOCUS™ Program and my medical condition, and enroll me in appropriate assistance programs;
2. Contact my Providers regarding shipment and receipt of ONSOLIS™;
3. Contact my Providers to collect, enter, and maintain my Health Information in a database;
4. Submit information to government agencies and other authorities, such as the FDA, regarding such matters as adverse events and the FOCUS™ Program;
5. Contact my Insurers as needed to verify my insurance coverage, review reimbursement issues, and assist with adjudication of claims;
6. Further use and disclosure of my Health Information as required or permitted by applicable law; and
7. Use or disclosure of my de-identified Health Information (all personal identifiable information has been removed) as permitted by applicable law.

I understand that federal privacy laws may no longer protect my Health Information after its disclosure to BDSI/Meda and that it may be subject to re-disclosure. However, BDSI/Meda agree to protect my Health Information by using and disclosing it only for the purposes described.

I understand that I am not required to sign this Authorization. If I do not sign, I may not enroll in the FOCUS™ Program to receive ONSOLIS™ and may not receive the other services described above. Otherwise, my treatment, payment for treatment, insurance enrollment, or eligibility for insurance benefits will not be directly affected if I do not sign this Authorization.

I understand that I may revoke (withdraw) this Authorization at any time by sending a signed, written request to the FOCUS™ Program by:

- fax to 1-800-558-6302, or
- mail to PO Box 52024
Phoenix, AZ 85072.

BDSI/Meda shall notify my Providers and Insurers of my revocation, who may no longer disclose my Health Information to BDSI/Meda once they have received and processed that notice. However, revoking this Authorization will not affect BDSI's/Meda's ability to use and disclose my Health Information that it has already received to the extent permitted under applicable law. If I revoke this Authorization, I may no longer participate in the FOCUS™ Program to receive ONSOLIS™ and the other services described above.

This Authorization expires ten (10) years from the date that I enroll in the FOCUS™ Program.

I understand and agree with the terms and conditions of this Authorization. I also understand that I will receive a copy of this Authorization.

Wholesaler/Distributor Enrollment Form

The FOCUS™ Program for ONSOLIS™



I understand that ONSOLIS™ is available only through the FOCUS™ Program, I agree to comply with the program requirements, and acknowledge that:

1. I will ensure that relevant staff are trained about the FOCUS™ Program for ONSOLIS™ procedures.
2. I will ensure that relevant staff distribute ONSOLIS™ only to FOCUS™ pharmacies that are active in the database.
3. I will provide monthly records of ONSOLIS™ shipments for each FOCUS™ pharmacy to the FOCUS™ Program.
4. I will permit a program-related audit of our shipping records to corroborate that we are shipping ONSOLIS™ only to FOCUS™ pharmacies.

Wholesaler's/Distributor's Authorized Representative Signature

Date

Print Name

Title

Wholesaler Information

Wholesaler/Distributor Name _____

DEA Registration Number _____

Primary Ship to Address _____

City _____ State _____ Zip Code _____

Office Phone _____ Office Fax _____

Wholesaler/Distributor Point of Contact _____ Phone _____

Fax _____ E-mail _____

Please fax this completed form to the FOCUS™ Program for ONSOLIS™ at 1-800-558-6302.

For questions regarding the FOCUS™ Program for ONSOLIS™, call 1-877-466-7654 (1-877-4ONSOLIS).