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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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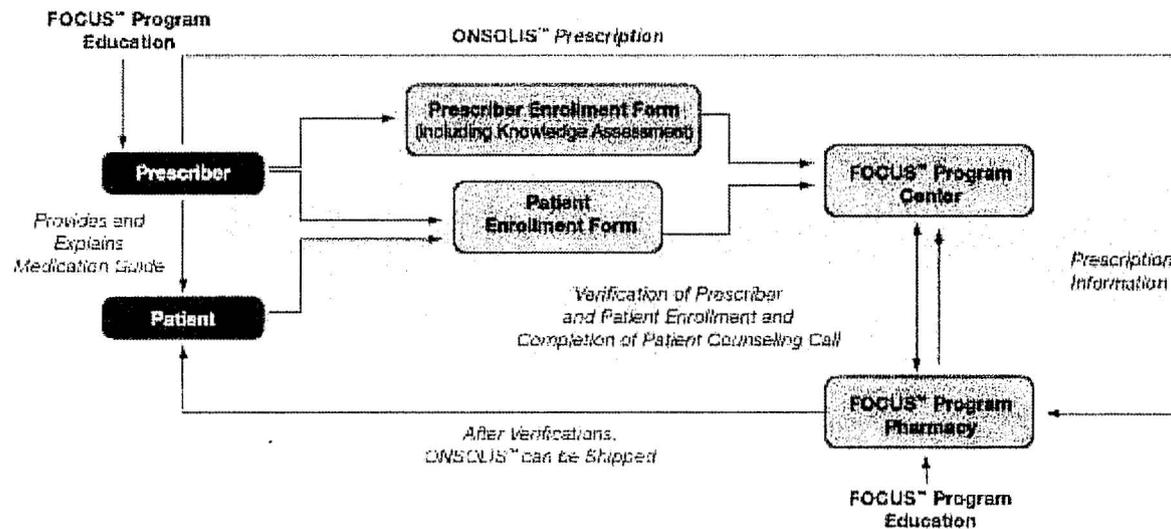
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Overview of The FOCUS™ Program for ONSOLIS™



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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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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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- 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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