

## Information for prescribers

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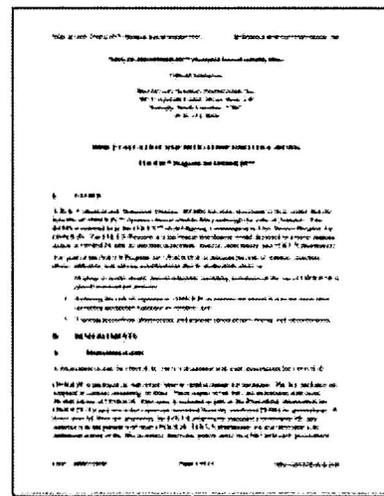
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Open this file for a better understanding of the goals and elements of the FOCUS™ Program.

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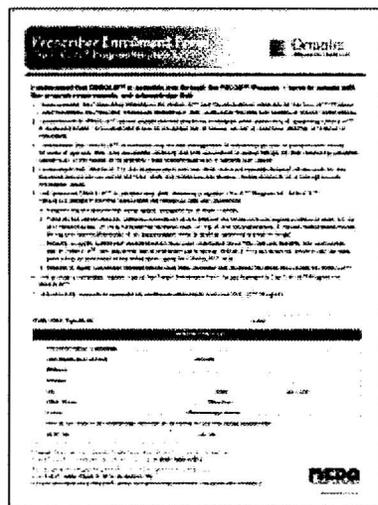
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## Information for prescribers

### Prescriber Enrollment Form



The image shows a thumbnail of the Prescriber Enrollment Form. The form is titled 'Prescriber Enrollment Form' and includes the Onsolis logo. It contains several sections of text, including a 'Knowledge Assessment' section with multiple-choice questions. The form is designed to be filled out by a prescriber and then faxed to the company.

[Click to open](#)

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

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

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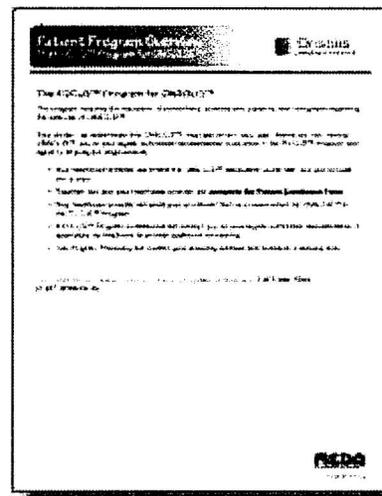
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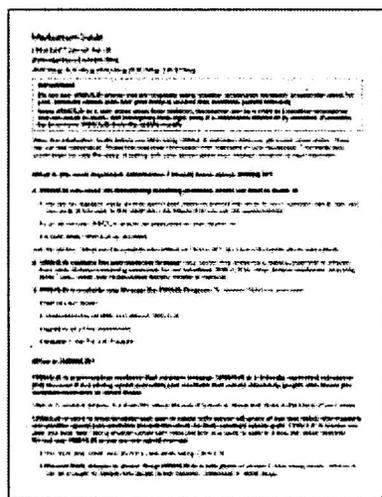
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This overview will help you describe the elements of the program to your patient.

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.

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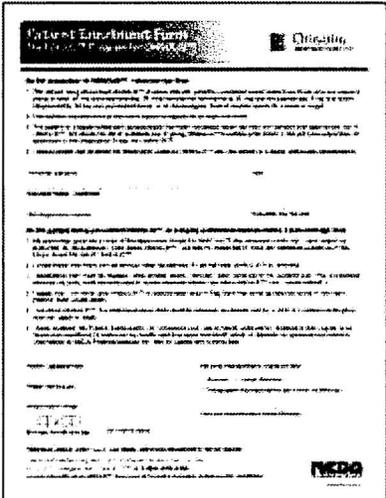
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The image shows a thumbnail of the Patient Enrollment Form. The form is titled "Patient Enrollment Form" and includes the Onsolis logo. It contains several sections of text, including a "WARNING" section and a "PATIENT INFORMATION" section. The form is designed to be signed by both the prescriber and the patient.

[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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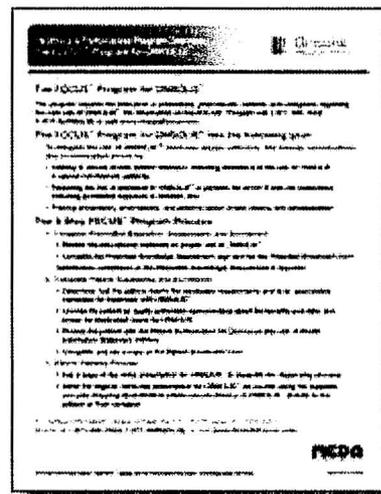
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## Information for pharmacists

### Healthcare Professional Program Overview



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

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## Information for pharmacists

### 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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## Information for pharmacists

### 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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