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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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Information for prescribers

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/saib_0401.pdf)

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