

Medication Guide

ONSOLIS™ (än-sō'-līs) **CII**
(fentanyl buccal soluble film)

200 mcg, 400 mcg, 600 mcg, 800 mcg, 1200 mcg

IMPORTANT:

Do not use ONSOLIS unless you are regularly using another opioid pain medicine around-the-clock for your constant cancer pain and your body is used to this medicine (opioid tolerant).

Keep ONSOLIS in a safe place away from children. Accidental use by a child is a medical emergency and can result in death. Get emergency help right away if a child takes ONSOLIS by accident. If possible, try to remove ONSOLIS from the child's mouth.

Read this Medication Guide before you start using ONSOLIS and each time you get a new prescription. There may be new information. Share this important information with members of your household. This Medication Guide does not take the place of talking with your doctor about your medical condition or your treatment.

What is the most important information I should know about ONSOLIS?

1. ONSOLIS can cause life-threatening breathing problems which can lead to death, if:

- you are not regularly using another opioid pain medicine around-the-clock for your constant cancer pain and your body is not used to this medicine. This means that you are not opioid tolerant;
- you do not use ONSOLIS exactly as prescribed by your doctor; or
- a child takes ONSOLIS by accident.

See the section “What are the possible side effects of ONSOLIS?” for more information about side effects.

2. ONSOLIS contains the pain medicine fentanyl. Your doctor may prescribe a starting dose that is different from other fentanyl-containing medicines. Do not substitute ONSOLIS for other fentanyl medicines, including Actiq* (also called oral transmucosal fentanyl citrate) or Fentora*.

3. ONSOLIS is available only through the FOCUS Program. To receive ONSOLIS, you must:

- talk to your doctor
- understand the benefits and risks of ONSOLIS
- agree to all of the instructions
- register in the FOCUS Program

What is ONSOLIS?

ONSOLIS is a prescription medicine that contains fentanyl. ONSOLIS is a federally controlled substance (CII) because it is a strong opioid (narcotic) pain medicine that can be abused by people who abuse prescription medicines or street drugs.

ONSOLIS contains fentanyl in a small film (about the size of a dime or nickel) that sticks to the inside of your cheek.

ONSOLIS is used to treat breakthrough pain in adults with cancer (18 years of age and older) who regularly use another opioid pain medicine around-the-clock for their constant cancer pain. ONSOLIS is started only after you

have been taking another opioid pain medicine and your body is used to it (you are opioid tolerant). **Do not use ONSOLIS if you are not opioid tolerant.**

- You must stay under your doctor's care while taking ONSOLIS.
- **Prevent theft, misuse or abuse. Keep ONSOLIS in a safe place** to protect it from being stolen. ONSOLIS can be a target for people who abuse opioid (narcotic) medicines or street drugs.
- **Never give ONSOLIS to anyone else**, even if they have the same symptoms you have. It may harm them or even cause death.
- **Selling or giving away this medicine is against the law.**
- **It is not known if ONSOLIS is safe and effective in children under the age of 18 years.**

ONSOLIS is only given to people who are:

- enrolled in the FOCUS Program
- opioid tolerant

Who should not use ONSOLIS?

Do Not Use ONSOLIS if you:

- Are not already taking another opioid pain medicine around-the-clock for your constant cancer pain
- Only have pain for a short time, pain from surgery, headache, migraine, or dental pain
- Are allergic to any of the ingredients in ONSOLIS. See the end of this Medication Guide for a complete list of ingredients in ONSOLIS.

What should I tell my doctor before starting ONSOLIS?

Tell your doctor about all of your medical and mental health problems, especially if you have:

- trouble breathing or lung problems such as asthma, wheezing or being short of breath
- a head injury or brain problem
- liver or kidney problems
- seizures (convulsions or fits)
- slow heart rate or other heart problems
- low blood pressure
- mental health problems such as major depression or hallucinations (seeing or hearing things that are not real)
- past or present drinking problem or alcoholism for you or a family member
- past or present drug abuse or addiction problems for you or a family member

Tell your doctor if you are:

- **Pregnant or planning to become pregnant.** ONSOLIS may harm your unborn baby.
- **Breast feeding.** ONSOLIS passes through your breast milk. It can cause serious harm to your baby. You should not use ONSOLIS while breast feeding.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Some medicines may cause serious or life-threatening medical problems when taken with ONSOLIS. Sometimes the doses of certain medicines and ONSOLIS may need to be changed if used together.

- Do not take any medicine while using ONSOLIS until you have talked with your doctor. Your doctor will tell you if it is safe to take other medicines while you are using ONSOLIS.
- Be very careful about taking other medicines that make you sleepy, such as other pain medicines or some depression medicines (antidepressants that make you sleepy), sleeping pills, anxiety medicines, tranquilizer medicines, or some allergy medicines (antihistamines that make you sleepy).

Know the medicines you take. Keep a list of your medicines to show your doctor and pharmacist.

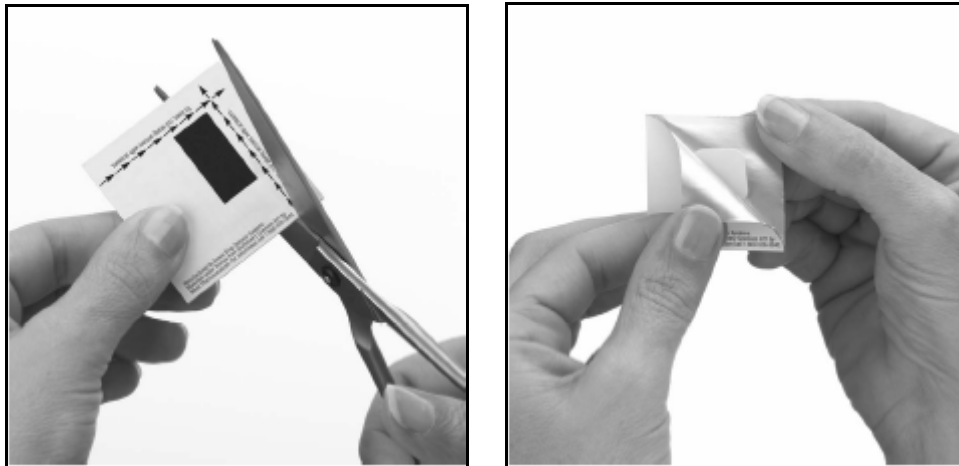
How should I use ONSOLIS?

- Before you can begin to receive ONSOLIS:
 - your doctor will explain the FOCUS Program to you
 - you will sign the FOCUS Patient Enrollment Form
 - you will receive counseling from the FOCUS Program call center
 - for more information about the FOCUS Program, go to www.OnsolisFocus.com or call 1-877-466-7654 (1-877-4ONSOLIS)
- ONSOLIS will be delivered directly to you from a special pharmacy.
- Use ONSOLIS exactly as prescribed by your doctor. Do not use ONSOLIS more often than prescribed.
 - Your doctor will change the dose until you and your doctor find the right dose for you.
 - ONSOLIS should be used only one time for each episode of breakthrough cancer pain. Separate doses of ONSOLIS by at least 2 hours.
 - Do not use ONSOLIS for more than four episodes of breakthrough cancer pain in one day. Talk to your doctor if you have more than four episodes of breakthrough pain each day. The dose of the opioid pain medicine for your constant pain may need to be changed.
 - Once the right dose for you has been found, do not change your dose of ONSOLIS yourself.
- Talk to your doctor if your dose of ONSOLIS does not relieve your breakthrough cancer pain. Your doctor will decide if your dose of ONSOLIS needs to be changed.
- ONSOLIS comes in a foil package. **Do not open the package until ready to use.** Once opened, use the entire ONSOLIS film right away.

To open an ONSOLIS package (as shown in [Medication Guide Figure A](#) below):

1. With the back side of the foil package facing you, cut along arrows with scissors.
2. Repeat step above to open the other side of the package.
3. Separate the layers of the foil package and remove the ONSOLIS film.

Medication Guide Figure A
Opening an ONSOLIS Foil Package



- **Do not chew or swallow ONSOLIS.** If you do, you will likely get less relief for your breakthrough cancer pain.
- **Do not cut or tear the ONSOLIS film.**
- To correctly use ONSOLIS (as shown in [Medication Guide Figure B](#) below):
 - Use your tongue to wet the inside of your cheek or, if needed, rinse your mouth with water to wet the area in your mouth where you will place ONSOLIS.
 - Hold the ONSOLIS film in place on a clean, dry finger with the **pink** side facing up.
 - Carefully **place** the ONSOLIS film inside your mouth with the pink side against the inside of your moistened cheek.
 - With your finger, **press** the ONSOLIS film against your cheek. Hold it there for 5 seconds.
 - Take your finger away from the ONSOLIS film. It will stick to the inside of your cheek.
 - Leave the film in place until it dissolves – usually within 15 to 30 minutes after you apply it.
 - You may drink liquids after 5 minutes.
 - If your doctor tells you to use more than one ONSOLIS film at the same time for your breakthrough cancer pain, do not put the films on top of each other. ONSOLIS films may be placed on either side of your mouth.
 - Avoid touching or moving the film while it dissolves.
 - Do not eat any food until after the film dissolves.

Medication Guide Figure B
Correct Administration of ONSOLIS



- If you can not take ONSOLIS this way, talk with your doctor about other choices to treat your breakthrough cancer pain.
- If you take too much ONSOLIS, you, your caregiver, or someone else nearby should call 911 for emergency help.

What should I avoid while taking ONSOLIS?

- **Do not drive, operate machinery, or do other dangerous activities** until you know how ONSOLIS affects you. ONSOLIS can make you sleepy. Ask your doctor when it is okay to do these activities.
- **Do not drink alcohol while using ONSOLIS.** It can increase your chance of having dangerous side effects.
- **Do not take any medicine while using ONSOLIS until you have talked with your doctor.** Your doctor will tell you if you can take other medicines while you are using ONSOLIS.
- **Be very careful about taking other medicines that make you sleepy** such as other pain medicines or some depression medicines (antidepressants that make you sleepy), sleeping pills, anxiety medicines, tranquilizer medicines, or some allergy medicines (antihistamines that make you sleepy).

What are the possible side effects of ONSOLIS?

You or a family member should call your doctor or get emergency medical help right away if you have any of the symptoms below:

- trouble breathing
- drowsiness with slow breathing
- slow, shallow breathing (little chest movement with breathing)
- feel faint, dizzy, confused, or have other unusual symptoms

These can be symptoms of an overdose of ONSOLIS. Your dose of ONSOLIS may be too high for you. **These symptoms may lead to serious problems or death if not treated right away. Do not take another dose of ONSOLIS.**

- **ONSOLIS can cause your blood pressure to drop.** This can make you feel dizzy if you get up too fast from sitting or lying down.

- **ONSOLIS can cause physical dependence.** Do not stop taking ONSOLIS or any other opioid without talking to your doctor. You could become sick with uncomfortable withdrawal symptoms because your body has become used to these medicines. Physical dependency is not the same as drug addiction.
- **There is a chance of abuse or addiction with ONSOLIS.** The chance is higher if you have ever been addicted to or abused other medicines, street drugs, or alcohol, or have a history of mental health problems.

The most common side effects of ONSOLIS are:

- nausea
- vomiting
- dizziness
- loss of too much body fluid (dehydration)
- shortness of breath
- sleepiness

Constipation (not often enough or hard bowel movements) is a very common side effect of pain medicines (opioids) including ONSOLIS and is unlikely to go away without treatment. Talk to your doctor about dietary changes, and the use of laxatives (medicines to treat constipation) and stool softeners to prevent or treat constipation while taking ONSOLIS.

Talk with your doctor about any side effects that bother you or do not go away. These are not all the side effects of ONSOLIS. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ONSOLIS?

- **Always keep ONSOLIS in a safe place away from children and from anyone for whom it has not been prescribed.** Protect it from theft.
- Store ONSOLIS at room temperature, 59 to 86°F (15 to 30°C) until ready to use.
- Do not freeze ONSOLIS.
- Keep ONSOLIS from getting wet (protect from moisture).

How should I dispose of unopened ONSOLIS films when they are no longer needed?

- Dispose of unopened ONSOLIS films as soon as you no longer need them:
 1. Remove the ONSOLIS film from its foil package.
 2. Drop the ONSOLIS film into the toilet.
 3. Repeat steps 1 and 2 for each ONSOLIS film. Flush the toilet after all unneeded films have been put into the toilet.
- Do not flush the ONSOLIS foil packages or cartons down the toilet.
- If you need help with disposal of ONSOLIS, call Meda Pharmaceuticals Inc. at 1-800-526-3840 or call your local Drug Enforcement Agency (DEA) office.

General information about the safe and effective use of ONSOLIS

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Use ONSOLIS only for the purpose for which it was prescribed. Do not give ONSOLIS to other people, even if they have the same symptoms you have.

ONSOLIS can harm other people and can even cause death.

Sharing ONSOLIS is against the law.

This Medication Guide summarizes the most important information about ONSOLIS. For more information talk with your doctor or pharmacist. You can ask your pharmacist or doctor for information about ONSOLIS that is written for healthcare professionals. For more information about ONSOLIS go to www.Onsolis.com or call Meda Pharmaceuticals Inc. at 1-800-526-3840.

What are the ingredients in ONSOLIS?

Active ingredient: fentanyl citrate

Inactive ingredients: carboxymethylcellulose, citric acid, hydroxyethyl cellulose, hydroxypropyl cellulose, methylparaben, monobasic sodium phosphate, peppermint oil, polycarbophil, propylene glycol, propylparaben, red iron oxide, sodium benzoate, sodium hydroxide, sodium saccharin, titanium dioxide, tribasic sodium phosphate, vitamin E acetate, and water.

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by Meda Pharmaceuticals Inc., Somerset, New Jersey, 08873 USA

Revised Mmmm, 20XX

This Medication Guide has been approved by the U.S. Food and Drug Administration.