

Medication Guide

Onsolis® (on sol is) **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 (this means that you are opioid tolerant).

Keep Onsolis in a safe place away from children.

Get emergency medical help right away if:

- **a child takes Onsolis. Onsolis can cause an overdose and death in any child who takes it.**
- **an adult who has not been prescribed Onsolis uses it.**
- **an adult who is not already taking opioids around-the-clock, uses Onsolis.**

These are medical emergencies that can cause death. If possible, try to remove Onsolis from the mouth.

Read this Medication Guide completely before you start using Onsolis, and each time you get a new prescription. There may be new information. This Medication Guide does not take the place of talking with your healthcare provider about your medical condition or your treatment. Be sure to share this information with members of your household and other caregivers.

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

Onsolis can cause life-threatening breathing problems which can lead to death.

- 1. Do not use Onsolis if you are not opioid tolerant.**
- 2. If you stop taking your around-the-clock opioid pain medicine for your constant cancer pain, you must stop using Onsolis.** You may no longer be opioid tolerant. Talk to your healthcare provider about how to treat your pain.
- 3. Use Onsolis exactly as prescribed by your healthcare provider.**
 - You must not take more than 1 dose of Onsolis for each episode of breakthrough cancer pain.
 - You must wait 2 hours before treating a new episode of breakthrough pain with Onsolis. See the Medication Guide section "How should I use Onsolis?" and the Patient Instructions for Use at the end of this Medication Guide for detailed information about how to use Onsolis the right way.
- 4. Do not switch from Onsolis to other medicines that contain fentanyl without talking with your healthcare provider.** The amount of fentanyl in a dose of Onsolis is not the same as the amount of fentanyl in other medicines that contain fentanyl. Your healthcare

provider will prescribe a starting dose of Onsolis that may be different than other fentanyl containing medicines you may have been taking.

5. **Do not** use Onsolis for short-term pain that you would expect to go away in a few days, such as:
- pain after surgery
 - headache or migraine
 - dental pain
6. **Never give Onsolis to anyone else**, even if they have the same symptoms you have. It may harm them or even cause death.

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

- **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.
 - **Selling or giving away this medicine is against the law.**
7. Onsolis is available only through a program called the **Transmucosal Immediate Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy (REMS) Access** program. To receive Onsolis, you must:
- talk to your healthcare provider
 - understand the benefits and risks of Onsolis
 - agree to all of the instructions
 - sign the Patient-Prescriber Agreement form

What is Onsolis?

- **Onsolis is a prescription medicine that contains fentanyl.**
- Onsolis is used to manage breakthrough pain in adults with cancer (18 years of age and older) who are already routinely taking other opioid pain medicines 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.
- Onsolis contains fentanyl in a small film (about the size of a dime or nickel) that sticks to the inside of your cheek.
- You must stay under your healthcare provider's care while using Onsolis.

Onsolis is only:

- available through the TIRF REMS Access program

- given to people who are opioid tolerant

It is not known if Onsolis is safe and effective in children under the age of 18 years.

Who should not use Onsolis?

Do not use Onsolis:

- **if you are not opioid tolerant.** **Opioid tolerant** means that you are already taking other opioid pain medicine around-the-clock for your constant cancer pain, and your body is used to these medicines.
- **for a short-term pain** that you would expect to go away in a few days, such as:
 - pain from surgery,
 - headache or migraine
 - dental pain
- if you are allergic to any of the ingredients in Onsolis. See near the end of this Medication Guide (before PATIENT INSTRUCTIONS FOR USE) for a complete list of ingredients in Onsolis.

What should I tell my healthcare provider before using Onsolis?

Before using Onsolis, tell your healthcare provider if you:

- have trouble breathing or lung problems such as asthma, wheezing or shortness of breath
- have or had a head injury or brain problem
- have liver or kidney problems
- have seizures
- have a slow heart rate or other heart problems
- have low blood pressure
- have mental health problems such as major depression, schizophrenia, or hallucinations (seeing or hearing things that are not real)
- have a past or present drinking problem (alcoholism) or a family history of drinking problems
- have a past or present drug abuse or addiction problem, or a family history of a drug abuse problem or addiction problem
- have any other medical conditions
- are pregnant or plan to become pregnant. Onsolis may cause serious harm to your unborn baby.
- are breastfeeding or plan to breastfeed. Onsolis passes through your breast milk. It can cause serious harm to your baby. You should not use Onsolis while breastfeeding.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Some medicines may cause

serious or life-threatening side effects 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 healthcare provider.** Your healthcare provider 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, anti-depressants, sleeping pills, anti-anxiety medicines, antihistamines, or tranquilizer.

Know the medicines you take. Keep a list of your medicines to show your healthcare provider and pharmacist when you get a new medicine.

How should I use Onsolis?

Before you can begin to use Onsolis:

- Your healthcare provider will explain the TIRF REMS Access program to you.
- You will sign the TIRF REMS Access Patient-Prescriber Agreement Form.
- Onsolis is only available at pharmacies that are part of the TIRF REMS Access program. Your healthcare provider will let you know the pharmacies where you can have your Onsolis prescription filled.

Using Onsolis:

- **Use Onsolis exactly as prescribed by your healthcare provider. Do not use Onsolis more often than prescribed.**
- Your healthcare provider will change the dose until you and your healthcare provider find the right dose for you. Do not change your dose of Onsolis yourself.
- Do not chew or swallow Onsolis.
- **You must not take a dose of Onsolis more than 1 time for each episode of breakthrough cancer pain.**
- You must wait at least **2** hours between doses before treating a new episode of breakthrough cancer pain with Onsolis.
- It is important for you to keep taking your around-the-clock opioid pain medicine while using Onsolis.
- Talk to your healthcare provider if your dose of Onsolis does not relieve your breakthrough cancer pain. Your healthcare provider will decide if your dose of Onsolis needs to be changed.
- You must not use Onsolis for more than four episodes of breakthrough cancer pain in one day. Talk to your healthcare provider if you have more than four episodes of breakthrough pain each day. The dose of the around-the-clock opioid pain medicine for your constant pain may need to be changed.
- If you use too much Onsolis or overdose, you or your caregiver should call for emergency medical help or have someone take you to the nearest hospital emergency room right away.

What should I avoid while using 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 healthcare provider 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.

What are the possible side effects of Onsolis?

Onsolis can cause serious side effects including:

1. **Breathing problems that can become life-threatening.** See “What is the most important information I should know about Onsolis?”
 - **You or a family member should call your healthcare provider or get emergency medical help right away if you: :**
 - have trouble breathing
 - have drowsiness with slowed breathing
 - have slow, shallow breathing (little chest movement with breathing)
 - feel faint, dizzy, confused, or have other unusual symptoms

These can be a sign that you have used too much Onsolis or the dose is too high for you. **These symptoms may lead to serious problems or death if not treated right away. If you have any of these symptoms, do not use any more Onsolis until you have talked to your healthcare provider.**

2. **Decreased blood pressure.** This can make you feel dizzy if you get up too fast from sitting or lying down.
3. **Physical dependence. Do not stop using Onsolis or any other opioid without talking to your healthcare provider.** 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.
4. **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

healthcare provider 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 healthcare provider about any side effect that bothers you or that does not go away.

These are not all the possible side effects of Onsolis. For more information, ask your healthcare provider 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 Onsolis from theft.
- Store Onsolis at room temperature, 59°F to 86°F (15°C to 30°C) until ready to use.
- Do not freeze Onsolis.
- Keep Onsolis dry.

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

- Dispose of any 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 healthcare provider or pharmacist. You can ask your pharmacist or healthcare provider for information about Onsolis that is written for healthcare professionals.

For more information about the TIRF REMS Access program, go to www.TIRFREMSaccess.com or call 1-866-822-1483.

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.

Patient Instructions for Use

Before you use Onsolis, it is important that you read the Medication Guide and these Patient Instructions for Use. Be sure that you read, understand, and follow these Patient Instructions for Use so that you use Onsolis the right way. Ask your healthcare provider or pharmacist if you have any questions about the right way to use Onsolis.

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:

1. With the back side of the foil package facing you, cut along arrows with scissors. (See figure A)
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. (See figure B)

Figure A

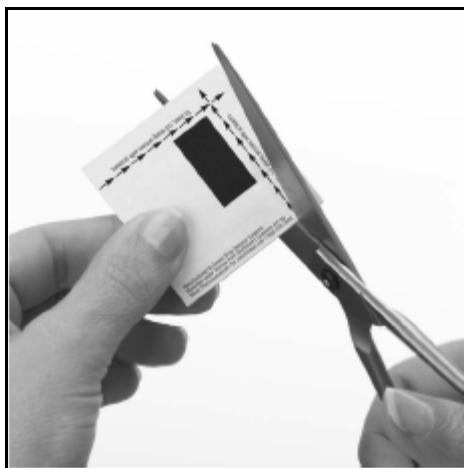
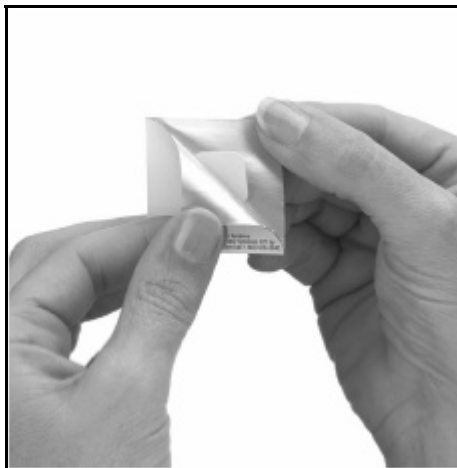


Figure B



- **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 (see figures 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. (See figure C)
- Carefully **place** the Onsolis film inside your mouth with the pink side against the inside of your moistened cheek. (See figure D)

- 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 healthcare provider 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.

Figure C



Figure D



If you can not use Onsolis this way, talk with your healthcare provider about other choices to treat your breakthrough cancer pain.

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

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