



[Home](#)

2. Subsys

# Subsys

**Generic name:** [fentanyl \(buccal/sublingual\)](#) [ *FEN-tan-il-BUK-al-/ sub-LIN-gwal* ]

**Brand names:** [Abstral](#), [Fentora](#), Subsys

**Drug class:** [Opioids \(narcotic analgesics\)](#)

Medically reviewed by [Philip Thornton, DipPharm](#). Last updated on Oct 24, 2023.

[Uses](#)   [Warnings](#)   [Before taking](#)   [Dosage](#)   [Side effects](#)   [Interactions](#)   [FAQ](#)

## What is Subsys?

Subsys spray is an opioid pain medication. An opioid is sometimes called a narcotic.

Subsys spray is used to treat "breakthrough" [cancer pain](#) that is not controlled by other medicines. Subsys is taken together with other non-fentanyl narcotic pain medicines that are used around the clock.

Subsys is not for treating pain that is not cancer-related.

## Warnings

Do not use Subsys to replace any other form of fentanyl, such as Actiq, Fentora, Onsolis, Duragesic, Lazanda, or generic brands of fentanyl (injection, skin patch, dissolving film, or "lollipop" device). Subsys is available only from a certified pharmacy under a special program. You must be registered in the program and understand the risks and benefits of taking this medication.

Do not use Subsys spray unless you are already being treated with a similar opioid pain medicine and your body is tolerant to it. Talk with your doctor if you are not sure you are opioid-tolerant.

Subsys is not for treating pain that is not cancer-related, such as pain from surgery or dental work, migraine headaches, or back pain.

Fentanyl can slow or stop your breathing, especially when you start using this medicine or whenever your dose is changed. Never take Subsys in larger amounts, or for longer than prescribed.

Some medicines can interact with fentanyl and worsen the effects on your breathing. Before using this medicine, tell your doctor if you are taking an antibiotic or any medicines to treat high blood pressure, heart rhythm disorders, depression, or viral infections such as hepatitis, HIV or AIDS.

**Fatal side effects can occur if you use this medicine with alcohol, or with other drugs that cause drowsiness or slow your breathing.**

Fentanyl may be habit-forming, even at regular doses. Take this medicine exactly as prescribed by your doctor. Never share the medicine with another person. **MISUSE OF NARCOTIC PAIN MEDICATION CAN CAUSE ADDICTION, OVERDOSE, OR DEATH**, especially in a child or other person using the medicine without a prescription.

## Before taking this medicine

**Do not use Subsys unless you are already using an around-the-clock opioid medicine and are tolerant to it.** You should not use Subsys if you are allergic to fentanyl, or if you have:

- severe asthma or other breathing problems; or
- a stomach or bowel obstruction (including paralytic ileus).

To make sure Subsys is safe for you, tell your doctor if you have ever had:

- breathing problems, sleep apnea;
- any type of breathing problem or lung disease;
- a head injury, brain tumor, or seizures;
- low blood pressure, slow heartbeats or other heart rhythm disorder;
- drug or alcohol addiction, depression, schizophrenia, or hallucinations;
- liver or kidney disease;
- urination problems; or
- problems with your thyroid, gallbladder, or pancreas.

Tell your doctor if there are children living in the home where you will store this medicine. **The amount of fentanyl in this medicine can be fatal to a child.**

**If you use Subsys while you are pregnant, your baby could become dependent on the drug.** This can cause life-threatening withdrawal symptoms in the baby after it is born. Babies born dependent on habit-forming medicine may need medical treatment for several weeks. Tell your doctor if you are pregnant or plan to become pregnant.

**Do not breast-feed** while you are using this medicine.

 [Subsys pregnancy and breastfeeding warnings](#) (more detail)

## How should I use Subsys?

Use Subsys exactly as prescribed by your doctor. Follow all directions on your prescription label. Fentanyl can slow or stop your breathing. Take this medicine exactly as prescribed by your doctor. Tell your doctor if the medicine seems to stop working as well in relieving your pain.

Fentanyl may be habit-forming. Never share this medicine with another person, especially someone with a history of drug abuse or addiction. **MISUSE OF NARCOTIC MEDICINE CAN CAUSE ADDICTION, OVERDOSE, OR DEATH, especially in a child or other person using the medicine without a prescription.** Selling or giving away fentanyl is against the law.

Read all patient information, medication guides, and instruction sheets provided to you. Ask your doctor or pharmacist if

you have any questions.

Do not use Subsys to replace any other form of fentanyl, such as Actiq, Fentora, Onsolis, Duragesic, Lazanda, or generic brands of fentanyl (injection, skin patch, dissolving film, or "lollipop" device).

If you switch to Subsys from another form of fentanyl, you will not use the same dose. You must start with the lowest dose (100 micrograms). Your doctor may change your dose to make sure you get the best results.

Point the Subsys spray nozzle into your mouth, lift your tongue, and spray the medicine under your tongue. Hold the liquid under the tongue for 30 to 60 seconds. Do not spit, swallow, or rinse your mouth during this time.

You may use a second dose of Subsys 30 minutes after the first. Use only the same strength and amount you used for the first dose. Call your doctor if you still have pain after taking the second tablet. Do not take more than 2 doses for each episode of breakthrough cancer pain.

You must wait at least 4 hours after your last dose of Subsys before you can treat a new pain episode.

Call your doctor if you have breakthrough pain more than 4 times in one day while using this medicine. **Do not treat more than 4 pain episodes per day with this medicine.**

Do not stop using Subsys suddenly, or you could have unpleasant withdrawal symptoms. Ask your doctor how to safely stop using this medicine.

Store at room temperature, away from heat and moisture. Do not freeze. Keep your medicine in a place where others cannot get to it. Keep track of the amount of medicine used. Fentanyl is a drug of abuse and you should be aware if anyone is using your medicine improperly or without a prescription.

Keep this medicine out of the reach of children or pets. **The amount of fentanyl in each Subsys spray unit can be fatal to a child or pet who accidentally sucks on or swallows it.** Seek emergency medical attention if this happens.

Carefully follow disposal instructions when this medicine is no longer needed. Dispose of used Subsys spray units in the disposal bags provided with this medication. Empty any unused spray units into the disposal bottle provided.

 [Detailed Subsys dosage information](#)

## What happens if I miss a dose?

Since Subsys is used for pain, you are not likely to miss a dose. Skip any missed dose if it is almost time for your next scheduled dose. Do not use extra medicine to make up the missed dose.

## What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222. **A fentanyl overdose can be fatal, especially in a child or other person using the medicine without a prescription.** Overdose symptoms may include extreme weakness or drowsiness, weak pulse, cold and clammy skin, pinpoint pupils, and slow breathing (breathing may stop).

## What should I avoid while using Subsys?

This medicine may impair your thinking or reactions. Avoid driving or operating machinery until you know how Subsys

will affect you. Dizziness or severe drowsiness can cause falls or other accidents.

**Do not drink alcohol.** Dangerous side effects or death could occur.

Grapefruit and grapefruit juice may interact with fentanyl and lead to unwanted side effects. Avoid the use of grapefruit products while taking Subsys.

## Subsys side effects

Get emergency medical help if you have **signs of an allergic reaction to Subsys**: hives; difficulty breathing; swelling of your face, lips, tongue, or throat.

**Like other narcotic medicines, fentanyl can slow your breathing. Death may occur if breathing becomes too weak.** A person caring for you should seek emergency medical attention if you have slow breathing with long pauses, blue colored lips, or if you are hard to wake up.

Call your doctor at once if you have:

- slow heart rate, sighing, shallow breathing, breathing that stops during sleep;
- severe drowsiness, feeling like you might pass out;
- confusion, extreme fear, unusual thoughts or behavior; or
- **low cortisol levels** - nausea, vomiting, loss of appetite, dizziness, worsening tiredness or weakness.

**Seek medical attention right away if you have symptoms of serotonin syndrome, such as:** agitation, hallucinations, fever, sweating, shivering, fast heart rate, muscle stiffness, twitching, loss of coordination, nausea, vomiting, or diarrhea.

**Serious side effects may be more likely in older adults and those who are malnourished or debilitated.**

Long-term use of opioid medication may affect fertility (ability to have children) **in men or women**. It is not known whether opioid effects on fertility are permanent.

Common Subsys side effects may include:

- headache, dizziness, drowsiness, pale skin, feeling weak or tired;
- constipation, nausea, vomiting; or
- swelling in your hands or feet.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

 [Subsys side effects](#) (more detail)

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## What other drugs will affect Subsys?

Some drugs can raise or lower your blood levels of fentanyl, which may cause side effects or make Subsys less effective. Tell your doctor if you also use certain antibiotics, antifungal medications, heart or blood pressure medications, or medicines to treat HIV or AIDS.

**Fentanyl can interact with many other drugs and cause dangerous side effects or death.** Be sure your doctor knows if you also use:

- cold or allergy medicines, bronchodilator asthma/COPD medication, or a diuretic ("water pill");
- medicines for motion sickness, irritable bowel syndrome, or overactive bladder;
- **other narcotic medications** - opioid pain medicine or prescription cough medicine;
- **a sedative like Valium** - diazepam, alprazolam, lorazepam, Xanax, Klonopin, Versed, and others;
- **drugs that make you sleepy or slow your breathing** - a sleeping pill, muscle relaxer, medicine to treat mood disorders or mental illness; or
- **drugs that affect serotonin levels in your body** - a stimulant, or medicine for depression, Parkinson's disease, migraine headaches, serious infections, or nausea and vomiting.

This list is not complete. Other drugs may interact with fentanyl, including prescription and over-the-counter medicines, vitamins, and herbal products. Not all possible interactions are listed in this medication guide.

 [Subsys drug interactions](#) (more detail)

## Does Subsys interact with my other drugs?

Enter medications to view a detailed interaction report using our [Drug Interaction Checker](#).

Subsys

+

Enter a drug name

Add

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## Patient resources

### Other brands

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## Professional resources

- [Subsys prescribing information](#)
- [FentaNYL, fentaNYL Citrate \(AHFS Monograph\)](#)

### Other brands

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## Related treatment guides

- [Breakthrough Pain](#)
- [Chronic Pain](#)

## Further information



Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use Subsys only for the indication prescribed.

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

[Medical Disclaimer](#)

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DRUG STATUS

<b>Availability</b>		
Rx	Prescription only	
<b>Pregnancy &amp; Lactation</b>		
	Risk data available	
<b>CSA Schedule*</b>		
2	High potential for abuse	▼
<b>Approval History</b>		
	Drug history at FDA	▼
<b>WADA Class</b>		
	Anti-Doping Classification	▼

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8.6 / 10

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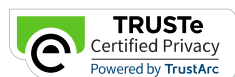
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