Fentanyl sublingual spray

MEDICATION GUIDE

NOTE: This sheet is a summary. It may not cover all possible information. If you have questions about this medicine talk to your doctor, pharmacist, or health care provider.

What is this medicine?

FENTANYL (FEN ta nil) is a pain reliever. It is used to treat breakthrough cancer pain that your long acting pain medicine does not control. Do not use this medicine for a pain that will go away in a few days like pain from surgery, doctor or dentist visits. The medicine is used only by people who have been taking an opioid or narcotic pain medicine for at least a week.

This medicine may be used for other purposes; ask your health care provider or pharmacist if you have questions.

How should I use this medicine?

This medicine is only for use in the mouth. Follow the directions on the prescription label. Open package with scissors right before use. Each unit contains enough medicine for one spray. Spray the medicine into the mouth underneath the tongue. Ask you doctor or health care provider if you have any questions. Do not take your medicine more often than directed.

A special MedGuide will be given to you by the pharmacist with each prescription and refill. Be sure to read this information carefully each time.

Talk to your pediatrician regarding the use of this medicine in children. Special care may be needed.

Patients over 65 years old may have a stronger reaction and need a smaller dose.

Overdosage: If you think you’ve taken too much of this medicine contact a poison control center or emergency room at once.

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What if I miss a dose?

This medicine is only used when needed for pain. Do not take double or extra doses.

What should I tell my health care provider before I take this medicine?

They need to know if you have any of these conditions:
• Brain tumor
• Head injury
• Heart disease
• History of a drug or alcohol abuse problem
• Kidney disease
• Liver disease
• Low blood pressure
• Lung or breathing disease, like asthma
• Mental illness
• Mouth sores
• Seizures
• An unusual or allergic reaction to fentanyl, other medicines, foods, dyes, or preservatives
• Pregnant or trying to get pregnant
• Breast-feeding

What may interact with this medicine?

• Alcohol
• Antihistamines
• Aprepitant
• Barbiturates, like phenobarbital
• Certain antibiotics like clarithromycin, erythromycin, and telithromycin
• Certain medicines for diabetes like pioglitazone and troglitazone
• Certain medicines for fungal infections like fluconazole, ketoconazole,itraconazole
• Certain medicines for seizures like carbamazepine, oxcarbazepine, phenytoin
• Cimetidine
• Diltiazem

NOTE: This medicine is only for you. Do not share this medicine with others.
What side effects may I notice from receiving this medicine?

Side effects that you should report to your doctor or health care professional as soon as possible:

- Allergic reactions like skin rash, itching or hives, swelling of the face, lips, or tongue
- Breathing problems
- Confusion
- Feeling faint or lightheaded, falls
- Hallucination
- Irregular heartbeat
- Loss of balance or coordination
- Trouble passing urine or change in the amount of urine
- Unusually weak or tired

Side effects that usually do not require medical attention (Report these to your doctor or health care professional if they continue or are bothersome.):

- Changes in taste
- Constipation
- Headache
- Loss of appetite
- Nausea, vomiting
- Sweating

This list may not describe all possible side effects. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

What should I watch for while using this medicine?

Tell your doctor or health care professional if your pain does not go away, if it gets worse, or if you have new or a different type of pain. You may develop tolerance to the medicine. Tolerance means that you will need a higher dose of the medicine for pain relief. Tolerance is normal and is expected if you take the medicine for a long time.

Do not suddenly stop taking your medicine because you may develop a severe reaction. Your body becomes used to the medicine. This does NOT mean you are addicted. Addiction is a behavior related to getting and using a drug for a non-medical reason. If you have pain, you have a medical reason to take pain medicine. Your doctor will tell you how much medicine to take. If your doctor wants you to stop the medicine, the dose will be slowly lowered over time to avoid any side effects.

There are different types of narcotic medicines (opiates) for pain. If you take more than one type at the same time, you may have more side effects. Give your health care provider a list of all medicines you use. Your doctor will tell you how much medicine to take. Do not take more medicine than directed. Call emergency for help if you have problems breathing.

You may get drowsy or dizzy. Do not drive, use machinery, or do anything that needs mental alertness until you know how this medicine affects you. Do not stand or sit up quickly, especially if you are an older patient. This reduces the risk of dizzy or fainting spells. Alcohol may interfere with the effect of this medicine. Avoid alcoholic drinks.

Your mouth may get dry. Chewing sugarless gum or sucking hard candy, and drinking plenty of water may help. Contact your doctor if the problem does not go away or is severe. This medicine may cause dry eyes and blurred vision. If you wear contact lenses you may feel some discomfort. Lubricating drops may help. See your eye doctor if the problem does not go away or is severe.

This medicine will cause constipation. Try to have a bowel movement at least every 2 to 3 days. If you do not have a bowel movement for 3 days, call your doctor or health care professional.

Where should I keep my medicine?
Keep out of the reach of children. This drug can be abused. Keep your medicine in a safe place to protect it from theft. Do not share this medicine with anyone. Selling or giving away this medicine is dangerous and is against the law.

Discard unused medicine and used packaging carefully. Pets and children can be harmed if they find used or lost packages. Follow the directions in the MedGuide.

Store at room temperature between 20 and 25 degrees C (68 and 77 degrees F). Keep this medication in the original container.

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