Fentanyl buccal tablet
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?
Take this medicine by mouth. Follow the directions on the prescription label. Do not remove a tablet from the blister until you are ready to use it. Peel the blister backing away to expose the tablet. Do not push the tablet through the blister. Place the tablet in your mouth between your cheek and gum and leave in place until the tablet is dissolved. After 30 minutes if there is any tablet left, swallow it with a glass of water. 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. While this drug may be prescribed for children as young as 16 years for selected conditions, precautions do apply. Patients over 65 years old may have a stronger reaction and need a smaller dose.

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

NOTE: This medicine is only for you. Do not share this medicine with others.

What if I miss a dose?
This medicine is only used when needed for pain.

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
• Breathing problems
• Drug abuse or addiction
• Head injury
• If you frequently drink alcohol containing drinks
• Kidney disease
• Liver disease
• Taken an MAOI like Carbex, Eldepryl, Marplan, Nardil, or Parnate in last 14 days
• An unusual or allergic reaction to fentanyl, other opioid analgesics, other medicines, foods, dyes, or preservatives
• Pregnant or trying to get pregnant
• Breast-feeding

What may interact with this medicine?
• Alcohol
• Antihistamines
• Barbiturates, like phenobarbital
• Clarithromycin, erythromycin
• General anesthetics
• Grapefruit juice
• Itraconazole, ketoconazole
• MAOIs like Carbex, Eldepryl, Marplan, Nardil, and Parnate
• Medicines for depression, anxiety, or psychotic disturbances
• Medicines for HIV
• Medicines for sleep
• Muscle relaxants
• Naltrexone
• Narcotic medicines ( opiates) for pain
• Phenothiazines like chlorpromazine, mesoridazine, prochlorperazine, thioridazine
• Verapamil

This list may not describe all possible interactions. Give your health care provider a list of all the medicines, herbs, non-
prescription drugs, or dietary supplements you use. Also tell them if you smoke, drink alcohol, or use illegal drugs. Some items may interact with your medicine.

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
- Changes in vision
- Confusion
- Dry mouth
- Feeling faint, lightheaded
- Hallucination
- Irregular heartbeat
- Mouth pain, sores
- Problems with balance, talking, walking
- Trouble passing urine or change in the amount of urine
- Unusual bleeding or bruising
- Unusually weak or tired

Side effects that usually do not require medical attention [report to your doctor or health care professional if they continue or are bothersome):

- Dizzy
- Headache
- Loss of appetite
- Nausea, vomiting
- Sweating
- Tingling in mouth

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.

If you develop problems breathing or slow breathing, remove this medicine from your mouth, and call emergency for help.

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. Unintended use by a child is an emergency and can result in death. If a child accidentally uses this medicine, get emergency help right away. 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.

Store at room temperature between 15 and 30 degrees C (59 and 86 degrees F). Throw away any unused medicine after the expiration date.

Discard unused medicine and used packaging carefully. Pets and children can be harmed if they find used or lost packages. Contact your health care provider or open blister pouches and flush the medicine down the toilet. Do not flush the blister pouches or boxes. Follow the directions in the MedGuide.
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