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Fentora Tablet, Effervescent

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Description

Side Effects Nausea, vomiting, constipation, lightheadedness, dizziness, drowsiness, or headache may occur. Pain, sores, or irritation in the mouth (where the medication has been applied) may also occur. Some of these side effects may decrease after you have been using this medication for a while. If any of these effects last or get worse, tell your doctor or pharmacist promptly. To prevent constipation, eat dietary fiber, drink enough water, and exercise. You may also need to take a laxative. Ask your pharmacist which type of laxative is right for you. To reduce the risk of dizziness and lightheadedness, get up slowly when rising from a sitting or lying position. Remember that this medication has been prescribed because your doctor has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. Tell your doctor right away if you have any serious side effects, including: interrupted breathing during sleep (sleep apnea), mental/mood changes (such as agitation, confusion, hallucinations), severe stomach/abdominal pain, difficulty urinating, signs of your adrenal glands not working well (such as loss of appetite, unusual tiredness, weight loss). Get medical help right away if you have any very serious side effects, including: fainting, seizure, slow/shallow breathing, severe drowsiness/difficulty waking up. This medication may increase serotonin and rarely cause a very serious condition called serotonin syndrome/toxicity. The risk increases if you are also taking other drugs that increase serotonin, so tell your doctor or pharmacist of all the drugs you take (see Drug Interactions section). Get medical help right away if you develop some of the following symptoms: fast heartbeat, hallucinations, loss of coordination, severe dizziness, severe nausea/vomiting/diarrhea, twitching muscles, unexplained fever, unusual agitation/restlessness. A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing. This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist. In the US – Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or at www.fda.gov/medwatch. In Canada – Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345. Uses This medication is used to help relieve sudden (breakthrough) cancer pain in people who are regularly taking moderate to large amounts of opioid pain medication. Fentanyl belongs to a class of drugs known as opioid analgesics. It works in the brain to change how your body feels and responds to pain. This medication should not be used to relieve mild or short-term pain (such as due to headache/migraine, dental procedures, surgery). How to use Fentora Tablet, Effervescent

Read the Medication Guide provided by your pharmacist before you start using fentanyl and each time you get a refill. Learn all usage and disposal instructions. If you have any questions, ask your doctor or pharmacist. Use this medication as directed by your doctor. Just before using, open the blister pack unit as directed. Do not push the tablet through the foil of the blister pack because this could damage the tablet. Place the tablet in your mouth either above a rear molar tooth between your upper cheek and gum or under the tongue. Leave the medication in place until it is dissolved (usually 14 to 25 minutes). Do not break, bite, chew, suck, or swallow the tablet whole. You may feel a gentle bubbling in your mouth while the tablet dissolves. Do not eat or drink anything while the tablet dissolves. If there is still some tablet left after 30 minutes, swallow it with a glass of water. If you are placing the tablet between your cheek and gum, remember to change sides of the mouth between doses. Avoid eating grapefruit or drinking grapefruit juice while using this medication unless your doctor or pharmacist says you may do so safely. Grapefruit can increase the chance of side effects with this medicine. Ask your doctor or pharmacist for more details. If you start to have side effects (such as dizziness, feeling sick to your stomach, severe drowsiness) before finishing a dose, your doctor may need to adjust your dose. Rinse your mouth with water and spit the rest of the tablet into a sink or toilet. Rinse the sink or flush the toilet afterward to finish proper disposal. Tell your doctor promptly if this happens. The dosage is based on your medical condition and response to treatment. If you need a second dose, wait 30 minutes after starting the first dose. Do not use more than 2 doses per episode of breakthrough pain. Wait at least 4 hours before using fentanyl buccal tablets again for another episode of breakthrough pain. Do not increase your dose, take the medication more often, or take it for a longer time than prescribed. Pain medications work best if they are used when the first signs of pain occur. If you wait until the pain has worsened, the medication may not work as well. You should continue to also take your long-acting opioid medication as directed by your doctor. Other pain relievers (such as acetaminophen, ibuprofen) may also be prescribed. Ask your doctor or pharmacist about using fentanyl safely with other drugs. Suddenly stopping this medication may cause withdrawal, especially if you have used it for a long time or in high doses. To prevent withdrawal, your doctor may lower your dose slowly. Tell your doctor or pharmacist right away if you have any withdrawal symptoms such as restlessness, mental/mood changes (including anxiety, trouble sleeping, thoughts of suicide), watering eyes, runny nose, nausea, diarrhea, sweating, muscle aches, or sudden changes in behavior. When this medication is used for a long time, it may not work as well. Talk with your doctor if this medication stops working well. Though it helps many people, this medication may sometimes cause addiction. This risk may be higher if you have a substance use disorder (such as overuse of or addiction to drugs/alcohol). Use this medication exactly as prescribed to lower the risk of addiction. Ask your doctor or pharmacist for more details. Tell your doctor if your pain does not get better or if it gets worse, or if you have more than 4 episodes of breakthrough pain daily, or if you need to use 2 doses of medication for each episode of pain. Warnings Fentanyl has a risk for abuse and addiction, which can lead to overdose and death. Fentanyl may also cause severe, possibly fatal, breathing problems. Do not use fentanyl buccal tablets unless you have been regularly taking moderate to large amounts of opioid pain medication. Otherwise, it may cause overdose (even death). To lower your risk, your doctor should have you use the smallest dose of fentanyl that works, and use it for the shortest possible time. See also How to Use section for more information about addiction. Ask your doctor or pharmacist if you should have naloxone available to treat opioid overdose. Teach your family or household members about the signs of an opioid overdose and how to treat it. The risk for severe breathing problems is higher when you start this medication and after a dose increase, or if you use the wrong dose/strength. Using this medication with alcohol or other drugs that can cause drowsiness or breathing problems may cause very serious side effects, including death. Be sure you know how to use fentanyl and what other drugs you should avoid using with it. Get medical help right away if any of these very serious side effects occur: slow/shallow breathing, unusual lightheadedness, severe drowsiness/dizziness, difficulty waking up. Carefully follow the specific directions for using fentanyl buccal tablets. Since they are not taken the same way, different forms of fentanyl (including lozenges, buccal tablets, patches) do not have the same effects at equal strengths and should not be substituted for each other. Tell your doctor or pharmacist of all medications that you use, especially of drugs that can affect how fentanyl works. Do not start, stop, or change the dosage of any medicines you are using without your doctor's approval. Keep this medicine in a safe place to prevent theft, misuse, or abuse. If someone accidentally swallows this drug, get medical help right away. To receive this medication in the United States, you must understand, agree to, and carefully follow the requirements of the TIRF REMS Program. If you live in

Canada or any other country, consult your doctor and pharmacist for your country's regulations. Before using this medication, women of childbearing age should talk with their doctor(s) about the risks and benefits. Tell your doctor if you are pregnant or if you plan to become pregnant. During pregnancy, this medication should be used only when clearly needed. It may slightly increase the risk of birth defects if used during the first two months of pregnancy. Also, using it for a long time or in high doses near the expected delivery date may harm the unborn baby. To lessen the risk, use the smallest effective dose for the shortest possible time. Babies born to mothers who use this drug for a long time may develop severe (possibly fatal) withdrawal symptoms. Tell the doctor right away if you notice any symptoms in your newborn baby such as crying that doesn't stop, slow/shallow breathing, irritability, shaking, vomiting, diarrhea, poor feeding, or difficulty gaining weight.

Precautions Before taking fentanyl, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details. Before using this medication, tell your doctor or pharmacist your medical history, especially of: brain disorders (such as head injury, tumor, seizures), breathing problems (such as asthma, sleep apnea, chronic obstructive pulmonary disease-COPD), kidney disease, liver disease, mental/mood disorders (such as confusion, depression), personal or family history of a substance use disorder (such as overuse of or addiction to drugs/alcohol), stomach/intestinal problems (such as blockage, constipation, diarrhea due to infection, paralytic ileus), difficulty urinating (such as due to enlarged prostate), gallbladder disease, disease of the pancreas (pancreatitis). This drug may make you dizzy or drowsy. Alcohol or marijuana (cannabis) can make you more dizzy or drowsy. Do not drive, use machinery, or do anything that needs alertness until you can do it safely. Avoid alcoholic beverages. Talk to your doctor if you are using marijuana (cannabis). Before having surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products). Older adults may be more sensitive to the side effects of this drug, especially confusion, dizziness, drowsiness, and slow/shallow breathing. During pregnancy, this medication should be used only when clearly needed. It may harm an unborn baby. Discuss the risks and benefits with your doctor. () This drug passes into breast milk and may have undesirable effects on a nursing infant. Tell the doctor right away if your baby develops unusual sleepiness, difficulty feeding, or trouble breathing. Consult your doctor before breast-feeding.

Overdose If someone has overdosed and has serious symptoms such as passing out or trouble breathing, give them naloxone if available, then call 911. If the person is awake and has no symptoms, call a poison control center right away. US residents can call their local poison control center at 1-800-222-1222. Canada residents can call a provincial poison control center. Symptoms of overdose may include: slow breathing, slow heartbeat, coma. Do not share this medication with others. Sharing it is against the law. This medication has been prescribed for your current condition only. Do not use it later for another condition unless told to do so by your doctor. A different medication may be necessary in that case. Not applicable. Store at room temperature away from light and moisture. Do not freeze. Do not store in the bathroom. Keep all medications away from children and pets. Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. For more details, read the Medication Guide, or consult your pharmacist or local waste disposal company.

Interactions Drug interactions may change how your medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval. Some products that may interact with this drug include: certain pain medications (mixed opioid agonist-antagonists such as butorphanol, nalbuphine, pentazocine), naltrexone, samidorphan. Other medications can affect the removal of fentanyl from your body, which may affect how fentanyl works. Examples include azole antifungals (such as itraconazole, ketoconazole), calcium channel blockers (such as diltiazem, verapamil), HIV protease inhibitors (such as nelfinavir), macrolide antibiotics (such as amoxil, zithromax, flagyl, levofloxacin, ciprofloxacin), mifepristone, nefazodone, rifamycins (such as rifabutin), ritonavir, certain drugs used to treat seizures (such as carbamazepine, phenytoin), among others. Taking MAO inhibitors with this medication may cause a serious (possibly fatal) drug interaction. Avoid taking MAO inhibitors (isocarboxazid, linezolid, metaxalone, methylene blue, moclobemide, phenelzine, procarbazine, rasagiline, safinamide, selegiline, tranlycypromine) during treatment with this medication. Most MAO inhibitors should also not be taken for two weeks before treatment with this medication. Ask your doctor when to start or stop taking this medication. The risk of

serious side effects (such as slow/shallow breathing, severe drowsiness/dizziness) may be increased if this medication is used with other products that may also cause drowsiness or breathing problems. Tell your doctor or pharmacist if you are taking other products such as other opioid pain or cough relievers (such as codeine, hydrocodone), alcohol, marijuana (cannabis), drugs for sleep or anxiety (such as alprazolam, lorazepam, zolpidem), muscle relaxants (such as carisoprodol, cyclobenzaprine), or antihistamines (such as cetirizine, diphenhydramine). Check the labels on all your medicines (such as allergy or cough-and-cold products) because they may contain ingredients that cause drowsiness. Ask your pharmacist about using those products safely. The risk of serotonin syndrome/toxicity increases if you are also taking other drugs that increase serotonin. Some examples are street drugs such as MDMA/ "ecstasy," St. John's wort, certain antidepressants (such as SSRIs like fluoxetine/paroxetine, SNRIs like duloxetine/venlafaxine), among others. The risk of serotonin syndrome/toxicity may be more likely when you start or increase the dose of these drugs. This medication may interfere with certain lab tests (such as amylase/lipase levels), possibly causing false test results. Make sure lab personnel and all your doctors know you use this drug.

Side Effects

Uses

Interactions

Other Details
