

Brightside Specialty Pharmacy

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Patient Education for FENTANYL 50 MCG/HR PATCH



Not recommended for use in children < 2 yrs, unless directed Important to remove the old patch before applying a new patch Contains enough drug to be fatal in children; Keep out of reach May cause drowsiness or dizziness Use caution driving. Taking more than recommended dose may cause respiratory arrest. Dispense & explain patient package insert and medication guide. High doses of this opiate can harm opiate-naive users. Warn of the dangers of using a cut/damaged/broken/leaking patch.

Unless MD directs, do not use in kids less than 2 Remove old patch before applying a new patch Can be fatal to children Keep out of their reach May make you drowsy or dizzy. Drive with caution Taking a larger dose may cause breathing problems. Important to read patient package insert& med guide May cause toxic effect in non-opiate using patients Do not use a damaged, cut or broken patch.

.....Education Section.....

IMPORTANT:

HOW TO USE THIS INFORMATION: This is a summary and

does NOT have all possible information about this product. This information does not assure that this product is safe, effective, or appropriate for you. This information is not individual medical advice and does not substitute for the advice of your health care professional. Always ask your health care professional for complete information about this product and your specific health needs.

FENTANYL - TRANSDERMAL

(FEN-ta-nil)

COMMON BRAND NAME(S):

Duragesic

WARNING:

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 transdermal patches unless you have been regularly using 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. See also Drug Interactions section. 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.

Do not use this medication to relieve mild, short-term, or sudden pain (such as due to headache/migraine, dental/medical procedures), or pain after surgery (including same-day surgery when you do not need to stay in the hospital overnight). This medication is not for occasional ("as needed") use.

Since they are not used 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.

Carefully follow the manufacturer's instructions for using fentanyl transdermal patches. The patches are for use on the skin only. Raising your skin/body temperature, using cut or damaged fentanyl patches, or using the patch improperly (such as by chewing it) may cause fatal overdose. Avoid increasing your skin temperature at/near the application site by using products such as heating pads, electric blankets, hot tubs, heat lamps, or tanning lamps. Avoid taking hot baths and sunbathing. However, you may bathe, shower, or swim while wearing the patch as long as you avoid hot water.

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.

Keep this medicine in a safe place to prevent theft, misuse, or abuse. This medication is not recommended for use by children younger than 2 years. Some manufacturers recommend that this

product should not be used by children younger than 18 years. If someone accidentally swallows this drug, get medical help right away.

USES:

This medication is used to help relieve severe ongoing

pain (such as due to cancer). 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.

Do not use the patch form of fentanyl to relieve pain that is mild or that will go away in a few days. This medication is not for occasional ("as needed") use.

HOW TO USE:

See also Warning section.

Read the Medication Guide and, if available, the Instructions for Use provided by your pharmacist before you start using this medication and each time you get a refill. Learn how to properly use, store, and discard the patches. If you have any questions, ask your doctor or pharmacist.

Use this medication on a regular schedule as directed by your doctor, not as needed for sudden (breakthrough) pain.

Before you start using this medication, ask your doctor or pharmacist if you should stop or change how you use your other opioid medication(s). It may take up to 24 hours before you have pain relief from fentanyl patches. Other pain relievers (such as acetaminophen, ibuprofen) may also be prescribed. Ask your doctor or pharmacist about using fentanyl safely with other drugs.

Apply this medication to the skin as directed by your doctor. Do not apply on burns, cuts, irritated skin, or skin that has been exposed to radiation (x-ray treatment). Select a dry, non-hairy area on a flat part of your body, such as the chest, sides, back, or upper arms. In young children or in people unable to think clearly (such as due to dementia), apply the patch on the upper back to lessen the chance it might be removed or placed in the mouth. If there is hair on the skin, use scissors to clip the hair as close as possible to the skin. Do not shave hair since this might cause skin irritation. If needed, use water to clean the area. Do not use soap, oils, lotions, or alcohol on the application site. Dry the skin well before applying the patch.

The patch is usually changed every 72 hours. To avoid irritation, apply to a different area each time. Be sure to remove the old patch before applying a new patch. The used patch still contains enough fentanyl to cause serious harm, even kill a child or pet, so fold it in half with the sticky sides together and discard properly. Do not let children see you apply a patch, and do not apply the patch where children can see it. Children have found patches that have fallen off or removed patches on sleeping adults and put them in their mouths or on their bodies with fatal results. (See also Warning section).

Do not use the patch if it appears to be broken, cut, or damaged. Remove from the sealed pouch, peel off the protective liner, and apply right away to the skin. Press firmly in place with the palm of the hand for 30 seconds, making sure the contact is complete (especially around the edges). If your prescribed dose is for more than one patch, make sure the edges of the patches do not touch or overlap. Wash your hands after applying

the patch.

If you have problems with the patch not sticking at the application site, you may tape the edges in place with first aid tape. If this problem lasts, ask your doctor for advice. If the patch falls off before 72 hours, a new patch may be applied to a different skin site. Be sure to let your doctor know if this happens.

If you accidentally touch the sticky layer to your skin or handle a cut or damaged patch, wash the area well with clear water. If the patch comes off and accidentally sticks to the skin of another person, immediately remove the patch, wash the area with water, and get medical help for them right away. Do not use soap, alcohol, or other products to wash the area.

The dosage is based on your medical condition and response to treatment. Do not apply more patches than directed, change them more frequently, or use them for a longer time than prescribed.

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.

SIDE EFFECTS:

See also Warning section.

Nausea, vomiting, constipation, lightheadedness, dizziness, drowsiness, or headache may occur. Mild irritation, itching, or redness at the application site 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, slow/fast/pounding heartbeat, 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.

PRECAUTIONS:

Before using fentanyl, tell your doctor or

pharmacist if you are allergic to it; or to adhesives; 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), disease of the pancreas (pancreatitis), gallbladder disease, slow/fast/irregular heartbeat.

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).

Tell your doctor promptly if you develop a fever, since this rise in body temperature may cause overdose (see also Warning section). Avoid activities that might cause your body temperature to rise. (such as doing strenuous work/exercise in hot weather).

Before having surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products).

If you are going to have an MRI test, tell testing personnel that you are using this patch. Some patches may contain metals that can cause serious burns during an MRI. Ask your doctor whether you will need to remove your patch before the test and apply a new patch afterward, and how to do so properly.

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. (See also Warning section.)

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.

DRUG INTERACTIONS:

See also Warning section.

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, ritonavir), macrolide antibiotics (such as erythromycin), nefazodone, mifepristone, rifamycins (such as rifabutin), 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, tranylcypromine) 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 laboratory tests (including amylase/lipase levels), possibly causing false test results. Make sure laboratory personnel and all your doctors know you use this drug.

OVERDOSE:

This medication patch may be harmful if chewed or swallowed. If someone has overdosed, remove the patch if possible. For 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/shallow breathing, slow heartbeat, coma.

NOTES:

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.

MISSED DOSE:

If you leave a patch on for more than 3 days (72 hours), remove the patch and apply a new patch as soon as you remember. Do not double the dose to catch up.

STORAGE:

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. See also Warning section.

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 (see also How to Use section). For more details, read the Instructions for Use, or consult your pharmacist or local waste disposal company.

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