

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**

**PATIENT MEDICATION INFORMATION**

**N FENTANYL PATCH**

Fentanyl Transdermal Patches (Matrix)

Read this carefully before you start taking **Fentanyl Patch** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Fentanyl Patch**.

**Serious Warnings and Precautions**

- **Even if you take Fentanyl Patch as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to overdose and death.**
- **Life-threatening breathing problems can happen while taking Fentanyl Patch, especially if not taken as directed.**
- **Never give anyone your Fentanyl Patch. They could die from taking it. Touching the medicated side of a patch can cause a fatal overdose to people who have not been prescribed this medication, especially children. Avoid accidental contact between the patch and other people, especially when holding or caring for children.**
- **Babies born to mothers who have taken Fentanyl Patch (for short or long periods, in small or large doses) at the end of their pregnancy can suffer life-threatening withdrawal symptoms. This can occur in the days after birth and for up to 4 weeks after delivery. If your baby has breathing changes (weak, difficult or fast), is unusually difficult to comfort, has tremors (shakiness), or has increased stools, sneezing, yawning, vomiting, or fever, seek immediate medical help for your baby.**

**What is Fentanyl Patch used for?**

Fentanyl Patch is used for the long-term management of pain, when:

- the pain is severe enough to require daily, around-the-clock painkillers
- the doctor determines that other treatment options are not able to effectively treat your pain

Fentanyl Patch is NOT used (“as needed”) to treat pain that you only have once in a while.

## **How does Fentanyl Patch work?**

Fentanyl Patch is a painkiller belonging to the class of medicines known as opioids. It relieves pain by acting on specific nerve cells of the spinal cord and brain.

## What is Fentanyl Patch?

Fentanyl Patch is a thin, adhesive, rectangular patch that is placed on your skin. Fentanyl Patch delivers an opioid medicine called fentanyl continuously through the skin and into the bloodstream to control your pain around the clock.

## What to expect from Fentanyl Patch

Because the medicine in Fentanyl Patch is gradually released from the patch and slowly absorbed through the skin, do not expect immediate pain relief after you apply your first patch. During this initial period, your doctor may ask you to take additional pain medication until you experience the full benefits of Fentanyl Patch.

While most patients obtain adequate pain relief with fentanyl, your pain may vary and occasionally break through. This is not unusual. If this occurs, your doctor may prescribe additional pain medication.

It is important to let your doctor know whether or not your pain is under control. If you frequently need additional short-acting pain medication, or if pain is waking you at night, you may need a change in your Fentanyl Patch dose. **If you continue to have pain, call your doctor.**

Always follow your doctor's instructions carefully and do not change or stop your Fentanyl Patch medication without first consulting with your doctor.

## **What are the ingredients in Fentanyl Patch?**

Medicinal ingredients: fentanyl

Non-medicinal ingredients:

- Acrylic-vinylacetate copolymer adhesive
- polyethyleneterephthalate backing foil
- siliconized polyethyleneterephthalate release liner

## **Fentanyl Patch comes in the following dosage forms:**

Fentanyl Patch is a transdermal patch that comes in six strengths: 2.1 mg, 4.2 mg, 8.4 mg, 12.6 mg, and 16.8 mg fentanyl per patch, delivering 12, 25, 50, 75, and 100 mcg fentanyl per hour respectively for 72 hours.

## **Do not use Fentanyl Patch if:**

- you are allergic to Fentanyl Patch or any of the other ingredients of Fentanyl Patch
- your pain can be controlled by the occasional use of painkillers including those available without a prescription
- you have severe asthma, trouble breathing or other lung problems
- you have bowel blockage or narrowing of the stomach or intestines
- you are going to have, or recently had, a planned surgery

- you have never taken a strong opioid medication
- you are also taking MAO inhibitors (certain medicines used for treatment of depression) or have taken them in the last 14 days before treatment with Fentanyl Patch
- you have a head injury
- you are at risk for seizures
- you suffer from alcoholism
- you get sudden severe pain in your abdomen and the cause has not been diagnosed
- you are pregnant or plan to become pregnant or in labour
- you are breastfeeding
- you are under 18 years of age

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Fentanyl Patch. Talk about any health conditions or problems you may have, including if you:**

- have any other medical conditions (such as diseases of the heart, lung, brain, liver and kidney)
- have severe kidney or liver disease
- have problems with your pancreas
- have a head injury or brain tumour
- or a family member have a history of illicit or prescription drug or alcohol abuse
- have chronic and severe constipation

**Other warnings you should know about:**

**Driving and using machines:** Before you perform tasks which may require special attention, wait until you know how you respond to Fentanyl Patch. Drowsiness, dizziness, or lightheadedness, can especially occur after the first dose and when the dose is increased.

**Fever/exposure to heat sources:**

At high temperatures, greater than usual quantities of fentanyl can be released into your body. If you have a fever, you should contact your doctor, who may adjust your dose if necessary. Increased release of fentanyl can also result from direct exposure to heat sources.

Do not expose the patch area to **sources of heat** such as heating pads, electric blankets, heated waterbeds, heat lamps, saunas and hot tubs, intensive sunbathing, etc., as this may increase the drug's ability to go through the skin and therefore result in an overdose. This may also occur if you develop a fever.

**Tolerance**

Fentanyl Patch may lead to tolerance in the long run. It is therefore possible that your doctor will prescribe a higher dose of Fentanyl Patch after some time to produce the same result.

**Dependence**

There is a possibility that you may become dependent on Fentanyl Patch (fentanyl) with longer term use. Discuss with your doctor.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with Fentanyl Patch:**

- alcohol, including prescription and non-prescription medications containing alcohol. Do not drink alcohol while taking Fentanyl Patch. This can lead to drowsiness, depressed breathing, serious side effects or a fatal overdose
- other sedative drugs which may enhance the drowsiness caused by Fentanyl Patch
- other opioid analgesics (for pain)
- general anaesthetics (used during surgery)
- benzodiazepines (drugs used to help you sleep or to reduce anxiety)
- antidepressants (for depression and mood disorders) such as selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs). Do not take Fentanyl Patch with MAO inhibitors or if you have taken MAO inhibitors in the last 14 days before treatment with Fentanyl Patch
- drugs used to treat migraines (e.g. triptans)
- drugs used to treat serious mental or emotional disorders such as schizophrenia
- certain drugs used to treat convulsions (such as carbamazepine, phenobarbital or phenytoin)
- antihistamines (for allergies)
- anti-emetics (for prevention of vomiting)
- drugs used to treat muscle spasms and back pain
- anti-retroviral, anti-fungal and antibiotic drugs

Patients should not consume grapefruit juice while taking this medication as it may make the side effects worse.

**How to use Fentanyl Patch:**

**Fentanyl Patch should only be used on the skin.**

- Always remove the old patch before applying a new one. This is important to avoid overdose.
- Apply on clean, dry, intact, non-hairy area on your upper chest, upper back, or upper arm. If the area you choose has body hair, clip (do not shave) the hair close to the skin with scissors.
- If you need to clean the skin where the patch will be applied, use only clear water.

**Do not:**

- apply heat to the area before or after applying the patch.
- chew, swallow, put it in your mouth, or use the patch in any way other than on the skin.
- wear more than one patch at a time, unless your doctor tells you to.
- use the Fentanyl Patch patch if the seal is broken or the patch is cut, damaged or changed in any way.
- apply your patch in front of children since they may copy your actions
- exceed the dose recommended by your doctor.

**Usual Adult Starting Dose**

You should already be taking some type of strong opioid medication before you begin using Fentanyl Patch patches.

Dosage is individualized. Be sure to follow your doctor's dosing instructions exactly.

Your doctor will determine the strength of Fentanyl Patch you should use based on your own particular needs. Do not change your dose without consulting your doctor. Each patch can be used for up to 72 hours (3 days).

**How to apply Fentanyl Patch**

## Step 1



Each patch is sealed in its own protective pouch. Do not remove the patch from the pouch until you are ready to use it. When you are ready, tear open the pouch at the notched corner.

## Step 2



A stiff protective liner covers the sticky side of the patch – the side that will be put on your skin. Hold the liner at the edge and pull the patch from the liner. Try not to touch the sticky side of the patch. Throw away the liner.

## Step 3



Immediately after you have removed the liner, apply the sticky side of the patch to a dry area of your chest, back, flank or upper arm. Press the patch firmly on your skin with the palm of your hand for about 30 seconds.

Not all adhesive products stick to all patients. If the patch does not stick well, or loosens after application, tape only the edges down with first aid tape.

In the event that the patch falls off before 3 days or 72 hours, discard it (See Disposal) and put a new one on at a different skin site. Be sure to let your doctor know that this has happened, and do not replace the new patch until 3 days (72 hours) after you put it on (or as directed by your doctor).

- Step 4 Wash your hands, with water only, when you have finished applying the patch.
- Step 5 A special card is provided to help you remember when you last put on your patch. After putting on the patch, write the date and time on the card and then keep the card for future reference.
- Step 6. After wearing the patch for 3 days, or as directed by your doctor, remove it (see Disposal). Then choose a **different** place on your skin to apply a new patch and repeat steps 1 to 5 in order. **Do not apply the new patch to the same place as the last one until several days have lapsed.**

### **Water and Fentanyl Patch**

You can bathe, swim, or shower while you are wearing Fentanyl Patch. If the patch falls off, discard the patch properly (see Disposal) and apply a new one at a different skin site, making sure the new skin area you choose is dry. Be sure to let your doctor know that this has happened. Take note of the time you applied the new patch and change it only after the required number of hours.

### **Overdose:**

Signs of overdose may include abnormally slow or weak breathing, dizziness, confusion or extreme drowsiness.

If a person is having the above signs of overdose, check all areas of their skin and remove any patches. There may be more than one patch, if a previous patch was not removed. Wash the area with water and seek immediate emergency medical help.

**If you think you have taken too much Fentanyl Patch, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.**

### **Missed Dose:**

If a patch is left on for more than three days (72 hours), remove patch and apply a new patch following instructions given (see How to use Fentanyl Patch).

### **Discontinuation of Fentanyl Patch:**

Please do not suddenly stop taking Fentanyl Patch as it may cause unwanted side effects such as nausea, vomiting, diarrhea, anxiety and shivering. Your doctor can discuss the best way for you to stop taking Fentanyl Patch.

### **Refilling Prescriptions for Fentanyl Patch:**

A new written prescription is required from your doctor each time you need more Fentanyl Patch. Therefore, it is important that you contact your doctor before your current supply runs out.

### What are possible side effects from using Fentanyl Patch?

These are not all the possible side effects you may feel when taking Fentanyl Patch. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- Drowsiness, insomnia
- Dizziness, fainting
- Nausea, vomiting, poor appetite, dry mouth
- Headache
- Problems with vision
- Weakness, lack of coordination
- Itching, hives, skin irritations or inflammations
- Sweating
- Constipation
- Confusion
- Seeing, feeling, hearing or smelling things that are not there (hallucinations)
- Depression

Be aware that removing the patch does not completely remove the source of drug, as drug is deposited under the skin and will continue to be released into the bloodstream over the next hours after the patch is removed.

### Opioid Withdrawal Symptoms

Opioid withdrawal symptoms such as nausea, vomiting, diarrhea, anxiety and shivering are possible after converting from your previous opioid analgesic to Fentanyl Patch, or converting from Fentanyl Patch to another opioid. Contact your doctor if you experience these symptoms when switching to or from Fentanyl Patch.

Talk with your doctor or pharmacist about ways to prevent constipation when you start using Fentanyl Patch.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b><u>RARE</u></b> <b>Overdose:</b> hallucinations, confusion, inability to walk normally, slow or weak breathing, extreme sleepiness, sedation, or dizziness, floppy muscles/low muscle tone, cold and clammy skin.			√

<b>Serious side effects and what to do about them</b>			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>Respiratory Depression:</b> slow, shallow or weak breathing.			√
<b>Allergic Reaction:</b> rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing.			√
<b>Bowel Blockage (impaction):</b> abdominal pain, severe constipation, nausea.			√
<b>Withdrawal:</b> nausea, vomiting, diarrhea, anxiety, shivering, cold and clammy skin, body aches, loss of appetite, sweating.		√	
<b>Fast, Slow or Irregular Heartbeat:</b> heart palpitations.		√	
<b>Low Blood Pressure:</b> dizziness, fainting, light-headedness.	√		
<b>Seizures (convulsions)</b>			√
<b>Stevens-Johnson Syndrome:</b> Severe rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals.			√
<b>Serotonin Syndrome:</b> A combination of most or all of the following; agitation, tremor, confusion, restlessness, sweating, shaking, shivering, hallucinations, sudden jerking of the muscles, fast heartbeat, labile blood pressure, nausea, vomiting, diarrhea			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

### **Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### **Storage:**

Keep unused, used, or expired Fentanyl Patch in a secure place to prevent theft, misuse or accidental exposure.

Keep Fentanyl Patch in its protective pouch until you are ready to use it. Store Fentanyl Patch between 15 and 25°C. Do not refrigerate or freeze. Remember, the inside of your car can reach temperatures much higher than 25°C (77°F) on a sunny day. Do not carry pouch in your pocket as it may reach body temperature (36°C).

**Keep Fentanyl Patch out of the sight and reach of children and pets.**

### **Disposal:**

Before putting on a new Fentanyl Patch patch, remove the patch you have been wearing. Fold the used patch in half so the sticky side sticks to itself. If the drug adhesive layer accidentally contacts the skin, the area should be washed with clear water. A used Fentanyl Patch can be very dangerous for, or even lead to death in babies, children, pets, and adults who have not been prescribed Fentanyl Patch as a considerable amount of drug remains in the patch after use.

**Fentanyl Patch should never be thrown into household trash, where children and pets may find it.** It should be returned to a pharmacy for proper disposal.

**Wash your hands, with water only, after removing the patch.**

Dispose of any patches that are left over from your prescription as soon as they are no longer needed. Remove the left-over patches from their protective pouches and remove the protective liners. Fold the patches in half and return to a pharmacy for proper disposal.

### **Safety and handling:**

**Fentanyl Patch is sealed to keep the drug adhesive layer from getting on your hands or body. If the drug adhesive layer accidentally touches the skin, wash the area with large amounts of water. Do not use soap, alcohol, or other solvents as these may increase the drug's ability to go through the skin.**

**Serious medical consequences, including death, have occurred when patches were accidentally transferred to other people, for example while hugging, sharing a bed or moving a patient. If your patch dislodges and accidentally sticks to the skin of another**

**person, take the patch off immediately, wash the area with water, and get medical care for them right away. This is true for both fresh and used patches, as a considerable amount of drug remains in the patch after use.**

**If you want more information about Fentanyl Patch:**

- Talk to your healthcare professional
- For questions or concerns contact the manufacturer, Pro Doc Ltée ([www.prodoc.qc.ca](http://www.prodoc.qc.ca))
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the [Health Canada website](#); by calling Pro Doc Ltée at 1-800-361-8559, [www.prodoc.qc.ca](http://www.prodoc.qc.ca) or [info@prodoc.qc.ca](mailto:info@prodoc.qc.ca).

This leaflet was prepared by Pro Doc Ltée

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