A Clear Choice

Mylan Fentanyl Transdermal System ℂ

℞ only

A Guide to Proper Application and Use

Fentanyl transdermal system should be used ONLY by adults and children over the age of two who have persistent, moderate to severe chronic pain and are already using another strong opioid narcotic pain medicine around-the-clock, and have been using that medicine regularly for a week or longer. This is called being opioid-tolerant.

Medicine You Can Trust

Mylan FENTANYL TRANSDERMAL SYSTEM Ⓒ is a clear, thin patch that contains fentanyl — the same medicine that patients have taken for years in a name-brand prescription patch.

If you have used the name-brand fentanyl patch before, you will notice that the *Mylan* FENTANYL TRANSDERMAL SYSTEM (Patch) does not have a liquid-filled, drug reservoir. Instead, the fentanyl active ingredient is contained within the adhesive layer of the patch ... which eliminates the possibility of leakage associated with a liquid-filled patch.

Although it looks different, the *Mylan* FENTANYL Patch will deliver the same amount of fentanyl over the same time period as the name-brand patch. That's why the Food and Drug Administration (FDA) approved the *Mylan* FENTANYL TRANSDERMAL SYSTEM as an equivalent alternative to the name-brand patch.

Make sure you read and understand all the instructions for using the *Mylan* FENTANYL Patch. Do not use the *Mylan* FENTANYL Patch unless you understand everything. Talk to your health care provider if you have questions.

What You Need to Know

This booklet contains important information about fentanyl transdermal system. Read this information carefully before you start using fentanyl transdermal system. This information does not take the place of talking to your health care provider about your medical condition or your treatment. Only your health care provider can decide if fentanyl transdermal system is the right treatment for you. If you do not understand some of this information or have questions, talk with your health care provider.

Fentanyl is a very strong opioid narcotic pain medicine that can cause serious and life-threatening breathing problems. Serious and life-threatening breathing problems can happen because of an overdose or if the dose you are using is too high for you. Call your doctor right away or get emergency medical help if you:

- have trouble breathing, or have slow or shallow breathing
- have a slow heartbeat
- have severe sleepiness
- have cold, clammy skin
- feel faint, dizzy, confused, or cannot think, walk, or talk normally
- have a seizure
- have hallucinations

IMPORTANT:

- **Keep fentanyl transdermal system in a safe place away from children and pets. Accidental use by a child or pet is a medical emergency and may result in death. If a child or pet accidentally uses fentanyl transdermal system, get emergency help right away.**
- **Make sure you read "How to apply the *Mylan* FENTANYL Patch," which is contained within this booklet. Also, read the Medication Guide that comes with the fentanyl transdermal system before you start using it.**
- **Always use a fentanyl transdermal system the right way (as described in the Medication Guide and in this booklet). Fentanyl transdermal system can cause serious breathing problems and death, especially if it is used the wrong way.**
- **Fentanyl transdermal system is a federally controlled substance (Ⓒ) because it can be abused. Keep fentanyl transdermal system in a safe place to prevent theft. Selling or giving away fentanyl transdermal system may harm others, and is against the law.**
- **Tell your doctor if you (or a family member) have ever abused or been dependent on alcohol, prescription medicines, or street drugs.**

Please see the **Medication Guide** provided with your prescription for additional important information.

What Else MUST You Know…

You must always use fentanyl transdermal system the right way. **Fentanyl transdermal system can cause serious breathing problems and even death, if it is used the wrong way.** Read the following carefully:

- **Do not** use heat sources such as heating pads, electric blankets, heat lamps, tanning lamps, saunas, hot tubs, or heated waterbeds while wearing a fentanyl transdermal system.
- **Do not** take hot baths or sunbathe while wearing a fentanyl transdermal system.
- **Do not change your dose unless your doctor tells you to.** Your doctor may change your dose after seeing how the medicine affects you. Do not use fentanyl transdermal system more often than prescribed. Call your doctor if your pain is not well controlled with this medicine.
- **Do not stop using fentanyl transdermal system suddenly.** Stopping fentanyl transdermal system suddenly can make you sick with withdrawal symptoms, such as nausea, vomiting, diarrhea, anxiety, and shivering. If your doctor decides you no longer need fentanyl transdermal system, ask how to slowly reduce this medicine so you don't have withdrawal symptoms. Do not stop taking fentanyl transdermal system without talking to your doctor.
- **Do not wear more than one fentanyl transdermal system at a time,** unless your doctor tells you to do so.
- **Call your doctor right away if you get a fever higher than 102°F or your body temperature increases from exercise.** A fever or increase in body temperature may cause too much of the medicine in the fentanyl transdermal system to pass into your body.
- **If you use more fentanyl transdermal system than your doctor has prescribed, get emergency medical help right away.**
- Do not use fentanyl transdermal system for a condition for which it was not prescribed.

Answers to Important Questions

Who can use the *Mylan* FENTANYL Patch?

Fentanyl transdermal system is only for adults and children over the age of two with persistent, moderate to severe chronic pain who are already using another strong opioid narcotic pain medicine around-the-clock, and have been using the medicine regularly for a week or longer. This is called being opioid-tolerant. You should not use fentanyl transdermal system for pain that can be controlled with other medicines.

Who should NOT use the *Mylan* FENTANYL Patch?

You should not use the fentanyl transdermal system if you are not opioid-tolerant.

You should not use fentanyl transdermal system if:

- you need opioid pain medicine for only a short time
- you need relief of pain caused by surgery, medical or dental procedures
- your pain can be taken care of by occasional use of other pain medicines
- if you have asthma symptoms or have severe asthma

Fentanyl transdermal system should not be used in children under 2 years of age.

What should I do if the patch comes off and sticks to the skin of another person?

A fentanyl transdermal system must be used only on the skin of the person for whom it was prescribed. If the patch comes off and accidentally sticks to the skin of another person, take the patch off of that person right away, wash the area with water, and get medical care for them right away.

Please see the **Medication Guide** provided with your prescription for additional important information.

Answers to Important Questions (Cont'd.)

What should I tell my doctor before using the *Mylan* FENTANYL Patch?

Fentanyl transdermal system is not safe for everyone. Tell your doctor about all of your medical conditions. Tell your doctor if you are planning to become pregnant, are pregnant, or breast-feeding. Fentanyl transdermal system may cause serious harm to a baby. Tell your doctor about all the medicines you take. Some medicines may cause serious or life-threatening side effects when used with fentanyl transdermal system.

What are the possible side effects of the *Mylan* FENTANYL Patch?

Serious side effects include life-threatening breathing problems and low blood pressure. Common side effects include nausea, vomiting, constipation, dry mouth, sleepiness, confusion, weakness, sweating, and pain and redness where the patch was applied. Talk to your health care provider about any side effect that concerns you.

These are not all the possible side effects of fentanyl transdermal system. You may report side effects to FDA at 1.800.FDA.1088.

How should I store the *Mylan* FENTANYL Patch?

Keep the fentanyl transdermal system in its unopened protective pouch until you are ready to use it and store at 20° to 25°C (68° to 77°F). **Keep fentanyl transdermal system in a safe place out of the reach of children and pets.**

Can I drink alcohol while using the *Mylan* FENTANYL Patch?

No, you should not drink any alcohol while using fentanyl transdermal system. Alcohol can increase your chances of having serious side effects.

Can I drive while using the *Mylan* FENTANYL Patch?

Do not drive, operate heavy machinery, or do other possibly dangerous activities until you know how fentanyl transdermal system affects you. Fentanyl transdermal system can make you sleepy. Ask your doctor to tell you when it is okay to do these activities.

Can I share my *Mylan* FENTANYL Patch with others?

Do not give fentanyl transdermal system to other people, even if they have the same symptoms you have. Fentanyl transdermal system can harm other people and even cause death. Sharing fentanyl transdermal system is against the law.

Can I get the *Mylan* FENTANYL Patch wet?

Yes, you can bathe, swim or shower while you are wearing a fentanyl transdermal system.

Please see the **Medication Guide** provided with your prescription for additional important information.

How to Apply the *Mylan* FENTANYL Patch

Getting Started

- Each fentanyl transdermal system is sealed in its own protective pouch. Do not remove the patch until you are ready to use it.
- Do not use the patch if the pouch seal is broken or the patch is cut, damaged or changed in any way.
- Make sure the fentanyl transdermal system is the dose and size that has been prescribed for you.
- Choose the time of day that is best for you to apply fentanyl transdermal system. Change the patch at about the same time of day (3 days or 72 hours after you first applied it) or as directed by your doctor.

Finding the Best Place to Apply the Patch

For adults: Put the patch on the chest, back, flank (sides of the waist), or upper arm in a place where there is no hair (see Figures 1-4).

Figure 1

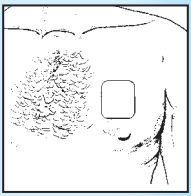


Figure 2

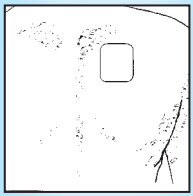


Figure 3

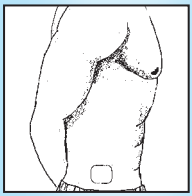
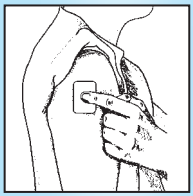


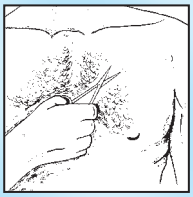
Figure 4



For children (and adults with mental impairment): Put the patch on the upper back (see Figure 2). This will lower the chances that a child will remove the patch and put it in his or her mouth.

For adults and children: Do not put a fentanyl transdermal system on skin that is very oily, burned, broken out, cut, irritated, or damaged in any way. Avoid sensitive areas or those that move around a lot. If there is hair, **do not shave (shaving irritates the skin)**. Instead, clip hair as close to the skin as possible (see Figure 5).

Figure 5



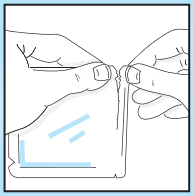
Talk to your doctor if you have questions about skin application sites.

Please see the **Medication Guide** provided with your prescription for additional important information.

Removing the Patch from the Foil Pouch

Before removing the patch from the pouch, clean the skin area with **clear water only. Pat skin completely dry**. Do not use anything on the skin such as soaps, lotions, oils, or alcohol before the patch is applied. After cleaning and drying the skin, follow these steps:

Figure 6

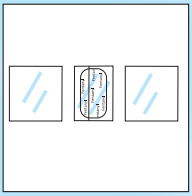


The patch is contained inside the foil pouch, which can be opened by tearing the indentations as illustrated in Figure 6. Do not use scissors because this could accidentally cut the patch.

Figure 7

Carefully remove the contents of the pouch (see Figure 7). Do not remove the patch from the pouch until you are ready to use it.

Figure 8



You will notice that there are three (3) individual components in the pouch. These include the *Mylan* FENTANYL Patch and two (2) clear pieces of plastic film, which protect the patch (see Figure 8). The two protective films and the foil pouch can now be discarded.

Simple "1, 2, 3" Application

Figure 9

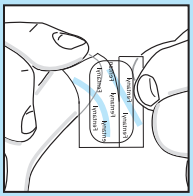


Figure 10

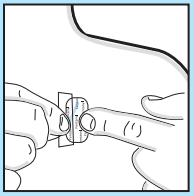
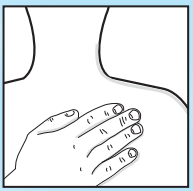


Figure 11



1. *Peel Away Only the Larger Side of the Clear Plastic Film*

As mentioned previously, the fentanyl active ingredient is contained within the adhesive layer of the patch, which is attached to a clear plastic film. You will notice that this protective film is divided in two pieces — one smaller and one larger.

Hold the patch with two hands so that the cut in the clear, plastic film is in a vertical (up and down) direction (see Figure 9). Peel away *only* the "larger" piece of protective film from the patch and throw it away. (NOTE: DO NOT PEEL AWAY BOTH PIECES OF THE PROTECTIVE FILM YET.) Touch the sticky side of the patch as little as possible.

2. *Place the Patch on the Skin*

Holding on to the "smaller" piece of protective film, apply the larger portion of the patch to the skin area that you previously cleaned and dried (see Figure 10). Press it down with your fingers or the palm of your hand.

3. *Remove the Smaller Side of the Clear Plastic Film (IMPORTANT: Use two hands for this step.)*

With one hand pressing down the larger portion of the patch already adhered to your skin, use your other hand to peel away the small protective film still on the patch. After you're through, press the entire patch down with your fingers or the palm of your hand for at least 30 seconds (see Figure 11). Throw away the other piece of protective film that you removed from the patch.

How to Apply the *Mylan* FENTANYL Patch (Cont'd.)

Making it Stick

Fentanyl transdermal system may not stick to all patients. You need to check the patches often to make sure that they are sticking well to the skin.

If the patch **falls off right away** after application, discard it properly and put a new one on at a different skin site.

If the fentanyl transdermal system is not sticking:

1. Apply first aid tape only to the edges of the patch.
2. If you continue to have problems with the patch not sticking, cover the patch with a special see-through adhesive dressing — Bioclusive® or Askina®Derm. Remove the backing from the dressing and place it carefully over the fentanyl transdermal system, smoothing it over the patch and your skin. **Never cover a fentanyl transdermal system with any other bandage or tape. For information on how to obtain the adhesive dressing, you may call 1.877.4.INFO.RX (1.877.446.3679).**

If your patch **falls off later**, but before 3 days (72 hours) of use, discard it properly 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).**

Other Important Information

- Wash your hands when you have finished applying a fentanyl transdermal system.
- Remove fentanyl transdermal system after wearing it for 3 days and **choose a different place on the skin** to apply a new fentanyl transdermal system.
- Remove the patch you are wearing before you apply a new patch.
- **Do not wear more than one fentanyl transdermal system at a time unless your doctor tells you to do so.**

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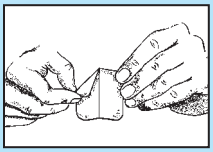
Proper Disposal is Key

It is very important that you NEVER throw a fentanyl transdermal system in a trash can. A used fentanyl transdermal system CAN be VERY dangerous for or even lead to death in babies, children, pets, and adults who have not been prescribed fentanyl transdermal system.

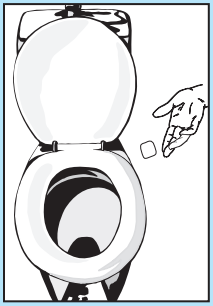
After removing a fentanyl transdermal system, follow these steps:

Figure 12



- Fold the used fentanyl transdermal system in half so that the sticky side sticks to itself (Figure 12).

Figure 13



- Flush the used fentanyl transdermal system down the toilet right away (Figure 13).

Throw away any fentanyl transdermal systems that are left over from your prescription as soon as they are no longer needed. Remove the leftover patches from their protective pouch and remove the protective liner. **Fold the patches in half with the sticky sides together, and flush the patches down the toilet.** Do not flush the pouch or the protective liner down the toilet. These items can be thrown away in a trash can.

Please see the **Medication Guide** provided with your prescription for additional important information.

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