DESCRIPTION

Fentanyl transdermal system is contraindicated in patients with known hypersensitivity to fentanyl or fentanyl-related substances. Fentanyl transdermal system should be prescribed only by persons knowledgeable in the continuous administration of opioid pain medication. Fentanyl transdermal system should ONLY be used in patients who are already receiving opioid therapy, and only if fentanyl is considered to be clinically indicated. Fentanyl transdermal system is contraindicated in patients who have a history of or are at risk for serious or life-threatening respiratory depression.

DOSAGE AND ADMINISTRATION

Fentanyl transdermal system is available in two strengths: 50 mcg/hr and 100 mcg/hr. The 50 mcg/hr system is intended for patients who require lower doses of fentanyl and the 100 mcg/hr system is intended for patients who require higher doses of fentanyl. The 50 mcg/hr system is dispensed in a 25 mcg/hr and 25 mcg/hr combination pack. The 100 mcg/hr system is dispensed in a 50 mcg/hr and 50 mcg/hr combination pack. The transdermal system is designed for application to the skin at the beginning of treatment and maintained for a period of 72 hours. The system contains a 25 mcg/hr or 50 mcg/hr fentanyl transdermal patch and one half of another transdermal patch providing the additional dose if required.

The transdermal system comes with a protective pouch and is designed to be applied to intact, non-scraped, non-inflamed skin. The system should be removed if the application site becomes sore or inflamed, if the patient has a temperature higher than 101°F (38.3°C), or if the patient has a fever or increased core body temperature due to strenuous exertion. The system is designed to release fentanyl transdermally through the skin into the systemic circulation per hour across average skin.

Nominal delivery rate per hour

Average delivery rate is approximately 1 mcg/hr.

Generic delivery rate is approximately 0.5 mcg/hr.

Average delivery rate is approximately 2 mcg/hr.

Generic delivery rate is approximately 1 mcg/hr.

Average delivery rate is approximately 3 mcg/hr.

Generic delivery rate is approximately 1.5 mcg/hr.

Average delivery rate is approximately 4 mcg/hr.

Generic delivery rate is approximately 2 mcg/hr.

Average delivery rate is approximately 5 mcg/hr.

Generic delivery rate is approximately 2.5 mcg/hr.

Average delivery rate is approximately 6 mcg/hr.

Generic delivery rate is approximately 3 mcg/hr.

Average delivery rate is approximately 7 mcg/hr.

Generic delivery rate is approximately 3.5 mcg/hr.

Average delivery rate is approximately 8 mcg/hr.

Generic delivery rate is approximately 4 mcg/hr.

Average delivery rate is approximately 9 mcg/hr.

Generic delivery rate is approximately 4.5 mcg/hr.

Average delivery rate is approximately 10 mcg/hr.

Generic delivery rate is approximately 5 mcg/hr.

Average delivery rate is approximately 11 mcg/hr.

Generic delivery rate is approximately 5.5 mcg/hr.

Average delivery rate is approximately 12 mcg/hr.

Generic delivery rate is approximately 6 mcg/hr.

Average delivery rate is approximately 13 mcg/hr.

Generic delivery rate is approximately 6.5 mcg/hr.

Average delivery rate is approximately 14 mcg/hr.

Generic delivery rate is approximately 7 mcg/hr.

Average delivery rate is approximately 15 mcg/hr.

Generic delivery rate is approximately 7.5 mcg/hr.

Average delivery rate is approximately 16 mcg/hr.

Generic delivery rate is approximately 8 mcg/hr.

Average delivery rate is approximately 17 mcg/hr.

Generic delivery rate is approximately 8.5 mcg/hr.

Average delivery rate is approximately 18 mcg/hr.

Generic delivery rate is approximately 9 mcg/hr.

Average delivery rate is approximately 19 mcg/hr.

Generic delivery rate is approximately 9.5 mcg/hr.

Average delivery rate is approximately 20 mcg/hr.

Generic delivery rate is approximately 10 mcg/hr.
FENTANYL TRANSDERMAL SYSTEM

Instructions for Applying a Fentanyl Transdermal System

Before Applying Fentanyl Transdermal System
• Each fentanyl transdermal system is sealed in its own protective pouch. Do not remove a fentanyl transdermal system from the pouch until you are ready to use it.
• Do not use a fentanyl transdermal system if the seal on the pouch is broken or the patch is cut, damaged, or changed in any way.
• Fentanyl transdermal systems are available in a different number of doses. Make sure you have the right dose patch or patches that have been prescribed for you.

Applying a Fentanyl Transdermal System

1. Skin Areas Where the Fentanyl Transdermal System May Be Applied
   For adults:
   • Put the patch on the chest, back, flank (side of the waist), or upper arm (Figure 1). Smoothen the patch over the skin to make sure the patch is in contact with the skin (Figures 2 and 3).
   • For children and adults with mental impairment:
     • Put the patch on the upper back (Figure 4). This will reduce the chance that the child will remove the patch and put it in their mouth.
     • Always ensure a patient airway is established and maintained, administer oxygen and assist or control respiration.

2. Prepare to Apply a Fentanyl Transdermal System:
• Choose the dose of drug that is best for you to apply fentanyl transdermal systems. Charge it at least 3 days before use.
• Do not remove more than one fentanyl transdermal system at a time unless your doctor tells you to do so (Figure 6).
• Clean the skin area with clear water (Figure 5).
• Do not use the skin area where you have already applied the fentanyl transdermal system, remove the patch you have been wearing.
• Clear the skin area with clear water only. Put skin adhesive remover, if available, on the skin area where you have already applied the fentanyl transdermal system.

3. Open the Pouch:
• Field and tear along the cut side of the pouch (Figure 7).
• Remove the protective liner from the patch (Figure 8).

4. Peel: Peel all the protection liner from the patch. Each fentanyl transdermal system has a clear plastic backing that can be peeled off. This provides a clear view of the fentanyl transdermal system's backing (Figure 9). Thrown the clear plastic backing away. Touch the sticky side of the fentanyl transdermal system to the skin area where you have already applied the fentanyl transdermal system (Figure 10).

5. Press:
• Press the patch onto the chosen skin site with the palm of your hand and hold for at least 10 seconds. Remove any air pockets from the patch with your fingers (Figure 11).
• The fentanyl transdermal system may not stick to all skin types. You may need to use medical tape to make sure the patch stays in the right place.