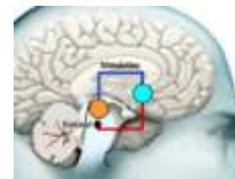
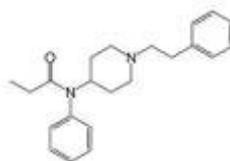


Rx **FENTANYL**
(Fentanyl is a potent synthetic
(man-made) narcotic)



GENERIC NAME: fentanyl transdermal system

cold, clammy skin; and slow heart rate.

DRUG CLASS AND MECHANISM

Fentanyl is a potent synthetic (man-made) narcotic. A 100 µg dose of fentanyl is approximately equal to 10 mg of morphine. Fentanyl stimulates receptors on nerves in the brain to increase the threshold to pain (the amount of discomfort that a person must feel in order to be considered painful) and reduce the perception of pain (the perceived importance of the pain). Fentanyl is available in transdermal (for application to the skin), transmucosal (for application to mucus membranes) and parenteral (injectable) forms. When applied to the skin of the upper torso, fentanyl is well absorbed. The amount of fentanyl in the blood increases gradually after topical application, reaching a peak after 12-24 hours. Once this concentration is achieved, blood concentrations remain constant over the 72 hours that the patch is worn. After removal of the patch, blood concentrations of fentanyl decrease slowly due to ongoing absorption of fentanyl remaining on the skin. Fentanyl was originally approved by the FDA for injection in 1968.

SIDE EFFECTS

This medication may cause constipation, lightheadedness, dizziness, drowsiness, stomach upset, nausea or flushing the first few days as your body adjusts to the medication. If these symptoms persist or become bothersome, inform your doctor. Notify your doctor if you develop: irregular or slow heartbeat, anxiety, tremors, seizures. If the area around the patch becomes red, itchy or irritated, try a new site. If the irritation continues or becomes worse, contact your doctor. When stopping this medication you may experience nausea, vomiting, diarrhea, anxiety, or shivering. If these symptoms persist or worsen, contact you doctor. In the unlikely event you have an allergic reaction to this drug, seek immediate medical attention. Symptoms of an allergic reaction include: rash, itching, swelling, dizziness, trouble breathing. If you notice other effects not listed above, contact your doctor or pharmacist.

GENERIC AVAILABLE: Yes

STORAGE

Patches should be stored at room temperature below 30°C (86°F). Used patches should be folded in half with the sticky sides together, and then flushed down the toilet. Patients must avoid exposing the patches to excessive heat as this promotes the release of fentanyl from the patch and increases the absorption of fentanyl through the skin which can result in fatal overdose.

PRESCRIPTION: Yes

WARNING

Because serious (sometimes fatal) breathing problems can occur, do not use this medication for short-term pain, pain occurring after surgery, or for mild or infrequent pain (on-and-off pain) relieved by less powerful pain medications. Do not use more fentanyl than prescribed by your doctor. The stronger doses of fentanyl (50mcg/hr or stronger) are for use only in patients that are already using narcotics for pain relief. Do not use this medication in children less than 12 years old nor in children less than 18 years that weigh less than 110lbs (50kg) except in a research setting. This medication should be used only for long-term (chronic) pain requiring continuous narcotic pain relief that is not helped by other less powerful pain medications or less frequent dosing. Seek immediate medical attention in the unlikely event that very slow, shallow breathing occurs.

PREPARATIONS: Transdermal systems labeled as delivering 50, 75, or 100 µg/hour.

USES

This medication is a narcotic analgesic used to relieve chronic pain.

HOW TO USE

The patch should be applied to a clean, dry area on the upper arm or back. If necessary, clip hair from the site prior to applying the patch. Remove the patch from the package, peel off the protective strip and immediately apply it to the site. Press firmly for 30 seconds to make sure the patch stays in place. Be sure the edges are held firmly to the skin. Wash your hands after applying the patch. Each patch may be worn continually for 72 hours even while showering or bathing. Remove the patch carefully and immediately flush it down the toilet. Apply each new patch to a different area to prevent skin irritation. This patch contains a very strong narcotic pain medication in gel form. If the gel should leak from the patch at any time, do not touch the gel. If you accidentally get some gel on you, wash the affected area with lots of water only. To remove the leaking patch, wear rubber gloves or use a tissue. Contact your pharmacist immediately for further instructions regarding proper patch disposal and replacement. Use this medication exactly as directed by your doctor. Do not increase your dose, use it more frequently or use it for a longer period of time than prescribed because this drug can be habit-forming. Also, if used for an extended period of time, do not suddenly stop using this drug without your doctor's approval. Over time, this drug may not work as well. Consult your doctor if this medication is not relieving the pain sufficiently.

PRECAUTIONS

Before using this medication, tell your doctor your medical history especially of: heart or lung disease, asthma, difficulty urinating, enlarged prostate, high blood pressure, low thyroid function, any drug allergies. Use caution when engaging in activities requiring alertness such as driving or using machinery. Limit alcohol consumption because it may add to the dizziness/drowsiness effects of this drug. Do not allow any heat source to warm the patch as it may cause the drug to be released too quickly. Caution is advised when using this drug in the elderly because they may be more sensitive to the effects of the drug. This drug should be used only when clearly needed during pregnancy. Discuss the risks and benefits with your doctor. Fentanyl passes into breast milk and may have undesirable effects on a nursing infant. Therefore, do not breast-feed without first consulting your doctor.

OVERDOSE

If overdose is suspected, remove the patch. Contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly. Symptoms of overdose may include slow, shallow breathing; drowsiness; deep sleep or loss of consciousness;



Taj Group of Companies ^{INDIA}

Taj Pharmaceuticals Ltd.

Phone : General EPA BX : 91 - (0)22 - 26374592/92 91,
(0)22 - 26374592/93 91 - (0)22 - 30601000,
Fax : 91-(0)22-26341274

Revised November 2010