



## Patient Information Sheet

### Fentanyl Transdermal System (marketed as Duragesic)

This is a summary of the most important information about the fentanyl skin patch. For details, talk to your healthcare professional.

---

#### FDA ALERT [7/2005]: Narcotic Overdose and Death

**FDA is looking into reports of death and other serious side effects from overdoses of the narcotic fentanyl in patients using the fentanyl transdermal skin patches for pain control. Directions for using the fentanyl skin patch must be followed exactly to prevent death or other severe side effects that can happen from using too much (overdosing) fentanyl. These directions are provided in the patient package insert, available at this link and highlighted below: <http://www.fda.gov/cder/drug/infopage/fentanyl/DuragesicPPI.pdf>**

*This information reflects FDA's preliminary analysis of data concerning this drug. FDA is considering, but has not reached a final conclusion about this information. FDA intends to update this sheet when additional information or analyses become available.*

---

#### What is the Fentanyl Transdermal System?

Fentanyl Transdermal System (skin patch) is a prescription medicine that is a federally controlled substance (CII) because it is a strong pain medicine that can be abused by people who abuse prescription medicines or street drugs.

- The fentanyl skin patch is only for patients with chronic (around the clock) pain that is moderate to severe and expected to last for weeks or longer.
- The fentanyl skin patch should not be the first opioid (narcotic) pain medicine that is prescribed for your pain. You should **ONLY** use the fentanyl skin patch if you have been taking at least 60 milligrams (mg) of oral morphine daily, or at least 30 mg of oral oxycodone daily, or at least 8 mg of oral hydromorphone daily, or an equally strong dose of another opioid for a week or longer before starting the fentanyl skin patch.
- The fentanyl skin patch is not for patients who need opioid pain medicines for only a short time. This includes the pain that happens with surgery (such as tonsillectomies), medical, or dental procedures (such as wisdom tooth removal).
- The fentanyl skin patch is not for occasional ("as needed") use.
- The fentanyl skin patch is only for opioid tolerant children 2 years of age or older who are already using other opioid narcotic pain medicines. Pediatric patients 2 years of age or older are opioid tolerant if

they are taking at least 60 milligrams (mg) of oral morphine daily, or at least 30 mg of oral oxycodone daily, or at least 8 mg of oral hydromorphone daily, or an equally strong dose of another opioid for a week or longer before starting the fentanyl skin patch.

#### Who Should Not Use the Fentanyl Skin Patch?

Do not use the fentanyl skin patch:

- If you are **NOT** already using other opioid narcotic medicines.
- If you need opioid pain medicines for only a short time.
- For pain from surgery, medical or dental procedures.
- If your pain can be taken care of by occasional use of other pain medicines.
- In children who are less than 2 years of age.
- In children 2 years of age or older who are not already using other opioid narcotic pain medicines (opioid tolerant).
- If you have acute (sudden) or severe asthma.
- If you have a gastrointestinal problem called paralytic ileus.

#### What are The Risks?

*The following are the major possible risks and side effects of fentanyl skin patch therapy. This list is not complete.*

The fentanyl skin patch can cause serious problems that you should tell your doctor or healthcare professional about immediately such as:

- **Trouble breathing**, which can be fatal. Call your healthcare professional right away or get emergency medical help if you:
  - Have trouble breathing
  - Have extreme drowsiness with slowed breathing
  - Have shortness of breath (little chest movement with breathing)
  - Feel faint, dizzy, confused, or have other unusual symptoms. These can be symptoms that you have taken too much (overdose) fentanyl or the dose of fentanyl in the skin is too high for you. These symptoms may lead to serious problems or death if not treated right away.
- **Physical Dependence**. Stopping the fentanyl skin patch suddenly can make you sick with withdrawal symptoms. Talk to your healthcare professional about slowly stopping the fentanyl skin patch.





## Patient Information Sheet

### Fentanyl Transdermal System (marketed as Duragesic)

- **Addiction.** There is a chance you could get addicted to the fentanyl skin patch. The chance is higher if you are or have been addicted to or abused other medicines, street drugs, or alcohol, or if you have a history of mental problems.
- **Drop in blood pressure.** This can make you feel dizzy if you get up too fast from sitting or lying down.
- **Common side effects** with the fentanyl skin patch are nausea, vomiting, constipation, dry mouth, sleepiness, confusion, weakness, and sweating.
- **Constipation** is a very common side effect of opioids including the fentanyl skin patch and is unlikely to go away without treatment. Talk to your healthcare professional about the use of laxatives (medicines to treat constipation) and stool softeners to prevent or treat constipation while using the fentanyl skin patch.
- **Sleepiness.** The fentanyl skin patch can make you sleepy. Do not drive, operate heavy machinery, or do any other possibly dangerous activities until you know how the fentanyl skin patch affects you.
- **Other:** Although uncommon, trouble sleeping and seizures were reported in children.
- Are breast feeding. The medicine in the fentanyl skin patch passes into your milk and can harm your baby.
- Use heating sources such as heating pads, electric blankets, heat lamps, saunas, hot tubs, or heated waterbeds. Do not take long hot baths or sun bathe. All of these can make your temperature rise and cause too much of the medicine in the fentanyl skin patch to be released at once and this can be dangerous.

#### What Should I Tell My Healthcare Professional?

**Before** you use the fentanyl skin patch, tell your healthcare professional about all of your medical problems, especially if you have:

- Trouble breathing or lung problems such as asthma, wheezing, or shortness of breath.
- A head injury or brain problems.
- A heart problem called bradycardia (slow heart beat).
- Liver or kidney problems.
- Seizures (convulsions or fits).
- Gallbladder problems.
- Low thyroid (hypothyroidism).
- Low blood pressure.
- Problems urinating.
- Major depression.
- Hallucinations (seeing or hearing things that are not seen by other people) adrenal gland problems such as Addison's disease.
- A past or present drinking problem or alcoholism, or a family history of this problem.
- A past or present drug abuse or addiction problem, or a family history of this problem.
- Skin reactions to the adhesives (glues) used in the fentanyl skin patch.
- Are pregnant or planning to become pregnant. The fentanyl skin patch may harm your unborn baby.

#### Can Other Medicines or Foods Affect the Fentanyl Skin Patch?

Some medicines may cause serious or life-threatening side effects when used with the fentanyl skin patch. Tell your healthcare professional about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements.

Sometimes, the doses of certain medicines and the fentanyl skin patch need to be changed when used together. Be especially careful about other medicines that make you sleepy such as other pain medicines, sleeping pills, anxiety medicines, antihistamines, or tranquilizers. Do not start any new prescription medicine, non-prescription medicine, or herbal supplement while using the fentanyl skin patch until you have talked to your healthcare professional.

#### What Else Should I know About the Fentanyl Skin Patch?

- Call your healthcare professional right away if you get a fever higher than 102°F. A fever may cause too much of the medicine in the fentanyl skin patch to pass into your body. Your healthcare professional may tell you to use a lower dose while you have a fever.
- Do not use the fentanyl skin patch if the seal is broken or the patch is cut, damaged or changed in any way. Using a patch that is cut, damaged, or changed in any way can expose you to the contents of the patch, which contains a potentially fatal dose of medicine.
- Do not change your dose or stop using the fentanyl skin patch unless your healthcare professional tells you to.
- Do not use the fentanyl skin patch more often than prescribed.
- Do not wear more than one fentanyl skin patch at a time, unless your healthcare professional tells you to do so.





## Patient Information Sheet

### Fentanyl Transdermal System (marketed as Duragesic)

- After you have stopped using a patch, be sure to fold the sticky sides of the patch together and flush it down the toilet. Do not put used fentanyl skin patches in a garbage can.
- If your healthcare professional tells you to stop using the fentanyl skin patch, throw away the unused packages. Open the unused packages and fold the sticky sides of the patches together, and flush them down the toilet.

