

CDER's Current Risk Communication Strategies

December 7, 2005

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President

National Research Center for

Women & Families

www.center4research.org

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News from CDER

- December 2. Mallinckrodt, Palatin Technologies and FDA notify healthcare professionals of postmarketing reports of serious and life-threatening cardiopulmonary events following the administration of NeutroSpec [Technetium (99m Tc) fanolesomab]. [MedWatch Safety Info.](#)
- December 1. Amgen, Ortho Biotech and FDA notify healthcare professionals of revision

Drug Safety

[About FDA's New Drug Safety Initiative](#)

**For Patients and
Healthcare
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Division of Drug Information

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Drug Information Pathfinder

Drug Approvals

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Drugs and Diseases

[MedlinePlus](#) (National Library of Medicine)

Clinical Trials

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Generic Drugs

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- [Orange Book](#)

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Drug Safety

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- [What You Should Know About Buying and Using Drug Products](#)

Drug Identification

- [DDI Drug ID service](#)
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Imports and Buying Drugs on the Internet

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Additional General Drug Information Links

Hot Topics at CDER

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Links to State Boards and Organizations

- [State Boards of Pharmacy](#)
- [State Medical Boards](#)
- [American Medical Association](#)
- [American Society of Health-Systems Pharmacists](#)

Top Drug Information Questions

- [Frequently Asked Questions of DDI Staff](#)
- [Frequently Asked Questions to CDER](#)

Still can't find the answer?

Visit the [DDI home page](#).
Contact CDER's Division of Drug Information.
druginfo@cder.fda.gov

1-888-INFO-FDA
1-888 463-6332 or (301) 827-4570

Division of Drug Information
5600 Fishers Lane, HFD-240
Rockville, MD 20857



Index to Drug-Specific Information

Information for a drug will be in one of three different formats:

- **Patient Information Sheet** (with and without FDA Alerts)
- **Consumer Information Sheet** (for drugs approved since 1998. These will all be eventually converted to Patient Information Sheets)
- **Drug Information Page** (may include a Patient or Consumer Information Sheet, approval information, FDA press releases, questions and answers about a drug, and other related information)

*This Index **does not** include all FDA approved drugs, only those with Information Sheets and Pages.*

Please use Drugs@FDA to search for information on a drug not found in the Index.



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.





FDA Alert for Healthcare Professionals

Fentanyl Transdermal Patch (marketed as Duragesic)

FDA ALERT [07/2005]: Narcotic Overdose and Death

FDA is investigating reports of death and other serious adverse events related to narcotic overdose in patients using the fentanyl transdermal patch for pain control. In June 2005 the Duragesic product label was updated to add new safety information in several areas of labeling, and a "Dear Healthcare Professional" letter about these changes was issued by the manufacturer that is available at this link

(http://www.fda.gov/medwatch/SAFETY/2005/duragesic_ddl.pdf). The directions for use of the fentanyl transdermal patch must be followed exactly to prevent death or other severe side effects from overdosing with fentanyl. These directions are provided in the product label and patient package insert at this link (<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.

To report any unexpected adverse or serious events associated with the use of this drug, please contact the FDA MedWatch program at 1-800-FDA-1088 or <http://www.fda.gov/medwatch/report/hcp.htm>

Recommendations

Health Care Professionals who prescribe the fentanyl transdermal patch should be fully aware of all the prescribing information in the product label. FDA is highlighting safety information from the product label here:

- **Fentanyl transdermal patches are potent opioid analgesics that may cause death from overdose. The fentanyl transdermal patch should always be prescribed at the lowest dose needed for pain relief.**
- **Fentanyl transdermal patches should not be used to treat short-term pain, pain that is not constant, or pain after an operation.** Fentanyl transdermal patches should only be used by opioid tolerant patients who are already taking other narcotic analgesics, and who have chronic pain that is not well controlled with shorter-acting analgesics.
- **Patients who are using the fentanyl transdermal patch and their caregivers must be fully informed about the directions for safe use of the patch.** These directions are provided in the product label and in the patient package insert, available at this link: <http://www.fda.gov/cder/drug/infopage/fentanyl/DuragesicPPI.pdf>.



*Report serious adverse events to FDA's MedWatch at 1-800-FDA-1088; or www.fda.gov/medwatch/report/hcp.htm
Questions? Call Drug Information, 1-888-INFO-FDA (automated) or 301-827-4570*

Druginfo@cderr.fda.gov



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Ortho Evra (norelgestromin/ethinyl estradiol) Information

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- [Questions and Answers](#) (11/10/2005)
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What are some possible side effects of Ortho Evra? *(This is NOT a complete list of side effects reported with Ortho Evra. Your health care provider can discuss with you a more complete list of side effects.)*

Some common side effects with combination hormonal contraceptives like Ortho Evra are:

- breast tenderness and enlargement
- headache
- nausea
- menstrual changes
- abdominal cramps and bloating
- vaginal discharge

Ortho Evra may also cause skin irritation at the application site.

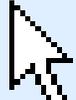
For more detailed information about Ortho Evra, ask your health care provider and pharmacist.

[Link to Ortho Evra's Labeling](#) 

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Posted: 11/22/02; Revised 8/8/2003



Posted: 11/22/02; Revised 8/8/2003 

Website with link to public health advisories

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FDA Public Health Advisory

Suicidality in Adults Being Treated with Antidepressant Medications

Several recent scientific publications suggest the possibility of an increased risk for suicidal behavior in adults who are being treated with antidepressant medications. Even before these reports became available, the FDA began a complete review of all available data to determine whether there is an increased risk of suicidality (suicidal thinking or behavior) in adults being treated with antidepressant medications. It is expected that this review will take a year or longer to complete. In the meantime, FDA is highlighting that:

No Date!



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FDA Public Health Advisory

Safety Warnings Regarding Use of Fentanyl Transdermal (Skin) Patches

FDA is investigating reports of death and other serious side effects from overdoses of fentanyl in patients using fentanyl transdermal (skin) patches for pain control. Deaths and overdoses have occurred in patients using both the brand name product Duragesic and the generic product. The directions for using the fentanyl skin patch must be followed exactly to prevent death or other serious side effects from overdosing with fentanyl. These directions are provided in the [product label and patient package insert](#). 

No Date!



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FDA Public Health Advisory

Elidel (pimecrolimus) Cream and Protopic (tacrolimus) Ointment

The FDA is issuing a public health advisory to inform healthcare providers and patients about a potential cancer risk from use of Elidel (pimecrolimus) and Protopic (tacrolimus), products that are applied to the skin. This concern is based on information from animal studies, case reports in a small number of patients, and how these drugs work. It may take human studies of ten years or longer to determine if use of Elidel or Protopic is linked to cancer. In the meantime, this risk is uncertain and FDA advises that Elidel and Protopic should be used only as labeled, for patients who have failed treatment with other therapies.

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FDA Public Health Advisory for Crestor (rosuvastatin)

Astra-Zeneca Pharmaceuticals today released a revised package insert for Crestor (rosuvastatin) for use in the 22 member states of the European Union (EU). The changes to the European labeling are in response to postmarketing spontaneous adverse event reports in patients receiving Crestor and highlight certain patient populations who may be at an increased risk for serious muscle toxicity (myopathy) associated with Crestor use, especially at the highest approved dose of 40 mg. These risk factors and many of the recommendations for how to minimize the risk of myopathy are already captured in the [FDA approved labeling for Crestor](#) in the U.S. FDA is alerting physicians to the need to carefully read the Crestor product label and follow the recommendations for starting doses, dose adjustments, and maximum daily doses to minimize the risk of myopathy in individual patients.

No date, and listed under incorrect year on website!



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- [Mifexprex](#) (mifepristone) (7/19/2005)
- [Duragesic](#) (Fentanyl Transdermal System) (7/15/2005)
- [Palladone](#) (hydromorphone hydrochloride, extended release capsules) (7/13/2005)
- [Suicidality in Adults Being Treated with Antidepressant Medications](#) (6/30/2005)
- [Deaths with Antipsychotics in Elderly Patients with Behavioral Disturbances](#) (4/11/2005)
- [FDA Announces Important Changes and Additional Warnings for COX-2 Selective and Non-Selective Non-Steroidal Anti-Inflammatory Drugs \(NSAIDs\)](#) (4/7/2005)
- [Crestor](#) (3/2/2005)
- [Elidel \(pimecrolimus\) Cream and Protopic \(tacrolimus\) Ointment](#) (3/10/2005)
- [Adderall](#) (2/9/2005)
- [Tysabri](#) (2/28/2005)
- [Gabitril](#) (2/18/2005)
- [Viramune](#) (1/19/2005)

Actual date of advisory

Date created: June 9, 2004



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FDA Public Health Advisory Sepsis and Medical Abortion

*November 4, 2005 Update: All four cases of fatal infection tested positive for *Clostridium sordellii*. In addition, FDA tested drug from manufacturing lots of mifepristone and misoprostol and found no contamination with *Clostridium sordellii*.*

July 19, 2005: The Food and Drug Administration (FDA) is aware of four cases of septic deaths in the United States, from September 2003 to June 2005 in women following medical abortion with mifepristone (Mifeprex) and misoprostol. The bacteria causing sepsis has been identified in two of the cases as *Clostridium sordellii*. The other two cases are under ongoing investigation by FDA along with the Centers for Disease Control and Prevention, State and local health departments, and the manufacturer of Mifeprex. All cases involve the off-label dosing regimen consisting of 200 mg of oral Mifeprex followed by 800 mcg of intra-vaginally placed misoprostol. The two confirmed cases of *Clostridium sordellii* did not have the usual signs and symptoms of an infection. Although these deaths are reported from California, all providers of medical abortion and their patients need to be aware of the risks of sepsis. As more information becomes available, FDA will alert the public.

Clear Date!



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FDA Public Health Advisory Suicidality in Children and Adolescents Being Treated With Antidepressant Medications October 15, 2004

Clear Date!

For additional information, please see the [Public Health Advisory, June, 2005](#)

Today the Food and Drug Administration (FDA) directed manufacturers of all antidepressant drugs to revise the labeling for their products to include a boxed warning and expanded warning statements that alert health care providers to an increased risk of suicidality (suicidal thinking and behavior) in children and adolescents being treated with these agents, and to include additional information about the results of pediatric studies. FDA also informed these manufacturers that it has determined that a Patient Medication Guide (MedGuide), which will be given to patients receiving the drugs to advise them of the risk and precautions that can be taken, is appropriate for these drug products. These labeling changes are consistent with the recommendations made to the Agency at a joint meeting of the Psychopharmacologic Drugs Advisory Committee and the Pediatric Drugs Advisory Committee on September 13-14, 2004.

The drugs that are the focus of this new labeling language are all drugs included in the general class of antidepressants; they are listed at the end of this Advisory.

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