



[FDA Home Page](#) | [Search FDA Site](#) | [FDA A-Z Index](#) | [Contact FDA](#)

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Actavis Recalls Remaining Fentanyl Patches in the US as Precaution

Contact:

Sarita Thapar, PharmD
908-659-2471

FOR IMMEDIATE RELEASE -- Morristown, NJ, March 1, 2008 -- Actavis Inc., the United States manufacturing and marketing division of the international generic pharmaceutical company Actavis Group hf, today announced that its subsidiary Actavis South Atlantic LLC is proceeding with the voluntarily recall from wholesalers and pharmacies of all lots of Fentanyl transdermal system CII patches sold in the United States.

This recall is an expansion of the Company's initial recall of fourteen lots of Fentanyl transdermal patches announced on February 17, 2008. That recall was due to the identification of a possible fold-over defect present in the product that potentially could cause leakage of the fentanyl gel. The remaining lots of Fentanyl transdermal system patches are being recalled as a precautionary measure because Actavis lacks assurance that all patches are free from defects.

All of the recalled patches were manufactured by Corium International Inc., a contract manufacturer for Actavis, and sold nationwide in the United States.

Fentanyl patches sold by Actavis in Europe are not affected by this recall.

As per the approved product labelling for Fentanyl transdermal system, fentanyl is a potent Schedule II opioid medication. Fentanyl patches that are leaking or damaged in any way should not be used. Exposure to fentanyl gel may lead to serious adverse events, including respiratory depression and possible overdose, which may be fatal. Anyone who comes in contact with fentanyl gel should thoroughly rinse exposed skin with large amounts of water only; do not use soap. Immediately dispose of affected patches that may be damaged or compromised in any way by flushing them down the toilet, using caution not to handle them directly. Damaged and/or compromised patches that have leaked gel will not provide effective pain relief.

Please note: Actavis South Atlantic LLC was formerly known as Abrika Pharmaceuticals Inc. The pouches containing the patches may be labelled with an Abrika Pharmaceuticals label, but the outer carton bears the Actavis logo with the following product names:

Actavis Fentanyl Transdermal System, 25 mcg/hr. NDC 67767-120-18.
Actavis Fentanyl Transdermal System, 50 mcg/hr. NDC 67767-121-18.
Actavis Fentanyl Transdermal System, 75 mcg/hr. NDC 67767-122-18.
Actavis Fentanyl Transdermal System, 100 mcg/hr. NDC 67767-123-18.

The lots covered by this recall have expiration dates between May 2009 and December 2009. Anyone who has fentanyl patches labelled with an Abrika or Actavis label should check them for

these expiration dates.

Anyone with Actavis Fentanyl transdermal system patches with the lot numbers listed on the schedule, should call 1 877 422 7452.

Patients using fentanyl patches who have medical questions should contact their health-care providers.

This recall is being conducted with the knowledge of the Food and Drug Administration.

Any adverse reactions experienced with the use of this product, and/or quality problems should also be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088, by Fax at 1-800-FDA-0178, by mail at MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/medwatch.

Fentanyl transdermal system is indicated for the management of persistent, moderate to severe chronic pain that requires continuous, around the clock opioid administration for an extended period of time and cannot be managed by other means such as non-steroidal analgesics, opioid combination products, or immediate release opioids.

Schedule

| Lot | Exp. Date | NDC | Strength |
|-------|-----------|--------------|----------|
| 27540 | Aug 09 | 67767-120-18 | 25mcg/hr |
| 27584 | Aug 09 | 67767-120-18 | 25mcg/hr |
| 27666 | Sep 09 | 67767-120-18 | 25mcg/hr |
| 27759 | Oct 09 | 67767-120-18 | 25mcg/hr |
| 27611 | Oct 09 | 67767-120-18 | 25mcg/hr |
| 27762 | Oct 09 | 67767-120-18 | 25mcg/hr |
| 27761 | Oct 09 | 67767-120-18 | 25mcg/hr |
| 27832 | Nov 09 | 67767-120-18 | 25mcg/hr |
| 27747 | Nov 09 | 67767-120-18 | 25mcg/hr |
| 27758 | Nov 09 | 67767-120-18 | 25mcg/hr |
| 27903 | Dec 09 | 67767-120-18 | 25mcg/hr |

| | | | |
|-------|--------|--------------|-----------|
| 27573 | Sep 09 | 67767-121-18 | 50mcg/hr |
| 27576 | Sep 09 | 67767-121-18 | 50mcg/hr |
| 27667 | Oct 09 | 67767-121-18 | 50mcg/hr |
| 27668 | Oct 09 | 67767-121-18 | 50mcg/hr |
| 27581 | Oct 09 | 67767-121-18 | 50mcg/hr |
| 27763 | Oct 09 | 67767-121-18 | 50mcg/hr |
| 27751 | Nov 09 | 67767-121-18 | 50mcg/hr |
| 27586 | Aug 09 | 67767-122-18 | 75mcg/hr |
| 27572 | Sep 09 | 67767-122-18 | 75mcg/hr |
| 27582 | Oct 09 | 67767-122-18 | 75mcg/hr |
| 27583 | Oct 09 | 67767-122-18 | 75mcg/hr |
| 27745 | Oct 09 | 67767-122-18 | 75mcg/hr |
| 27746 | Oct 09 | 67767-122-18 | 75mcg/hr |
| 27539 | Aug 09 | 67767-123-18 | 100mcg/hr |
| 27574 | Sep 09 | 67767-123-18 | 100mcg/hr |
| 27575 | Sep 09 | 67767-123-18 | 100mcg/hr |
| 27577 | Sep 09 | 67767-123-18 | 100mcg/hr |
| 27578 | Oct 09 | 67767-123-18 | 100mcg/hr |
| 27579 | Oct 09 | 67767-123-18 | 100mcg/hr |
| 27580 | Oct 09 | 67767-123-18 | 100mcg/hr |

| | | | |
|-------|--------|--------------|-----------|
| 27610 | Oct 09 | 67767-123-18 | 100mcg/hr |
| 27612 | Oct 09 | 67767-123-18 | 100mcg/hr |
| 27743 | Oct 09 | 67767-123-18 | 100mcg/hr |

#

[Firm Release](#) (Feb. 17, 2008)

[RSS Feed for FDA Recalls Information](#) [\[what's this?\]](#)

 [Sign up for Recall email updates.](#)

[FDA Newsroom](#)

[FDA Home Page](#) | [Search FDA Site](#) | [FDA A-Z Index](#) | [Contact FDA](#) | [Privacy](#) | [Accessibility](#)

[FDA Website Management Staff](#)