

# PHARMACY NEWSCAPSULE

Wisconsin Department of Health and Family Services  
Division of Quality Assurance

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## Methadone Advisory

*By: Doug Englebert, R.Ph*

The Food and Drug Administration (FDA) has received reports of death and life-threatening side effects in patients taking methadone. These side effects have occurred in patients newly starting methadone for pain control, and in patients who have switched to methadone after being treated for pain with other strong opioid pain relievers. Methadone can cause slow or shallow breathing and dangerous changes in heart beat that may not be felt by the patient.

In previous newsletters, I noted that the use of methadone for pain relief can be complicated, especially in the elderly. Methadone should only be prescribed for patients with moderate to severe pain when their pain is not ameliorated with other opioid pain relievers. Pain relief from a dose of methadone lasts about four to eight hours. However, methadone stays in the body much longer—from eight to 59 hours after it is taken and can vary over time in elderly patients. As a result, patients may feel the need for more pain relief before the methadone is gone from the body. Methadone may build up in the body to a toxic level if it is taken too often, if the amount taken is too high, or if it is taken with certain other medicines or supplements. Therefore, as discussed previously, methadone use requires close attention for dosage changes.

The FDA has issued a public health advisory to alert patients, their caregivers, and health care professionals to the following important safety information:

**Patients should take methadone exactly as prescribed.** Taking more methadone than prescribed can cause breathing to slow or stop and can result in death.

**Patients taking methadone should not start or stop taking other medicines or dietary supplements without talking to their health care provider.** Taking other medicines or dietary supplements may result in less pain relief. It may also cause a toxic buildup of methadone in the body leading to dangerous changes in breathing or heart beat that may cause death.

**Health care professionals and patients should be aware of the signs of methadone overdose.** Signs of methadone overdose include trouble breathing or shallow breathing, extreme tiredness or sleepiness; blurred vision; inability to think, talk, or walk normally; and feeling faint, dizzy, or confused. If these signs occur, patients should get medical attention right away.

*Adapted from the FDA Health Advisory*

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## New Medications

Brand Name	Generic Name	Use
Bystolic	Nebivolol	A beta-blocker medication for hypertension
Flector	Diclofenac	A nonsteroidal patch for acute pain due to strains, sprains, and contusion.

## Focus Medication By Doug Englebort, R.Ph. Fentanyl Patches

The FDA issued a public health advisory to alert patients, caregivers, and healthcare professionals to important information on the safe use of the fentanyl transdermal system; also known as the fentanyl patch (marketed as Duragesic and generics). The fentanyl patch is an opioid pain medicine applied to the skin for treating persistent, moderate to severe pain in opioid-tolerant patients who need to be on a narcotic pain medicine around-the-clock for more than a few days.

Despite issuing an advisory in July 2005, which emphasized the safe use of the fentanyl patch, the FDA continues to receive reports of death and life-threatening side effects in patients who use the fentanyl patch. The reports indicate that doctors have inappropriately prescribed the fentanyl patch to patients for acute pain following surgery, for headaches, occasional or mild pain, and other indications for which a fentanyl patch should not be prescribed. In addition, the reports indicate that patients are continuing to use the fentanyl patch incorrectly by replacing the patch more frequently than directed in the fentanyl patch instructions, applying more patches than prescribed, or applying a heat source to the patch; all of which can result in dangerously high fentanyl levels in the blood.

The fentanyl patch is only intended for treating persistent, moderate to severe pain in patients who are opioid-tolerant, meaning those patients who take a regular, daily, around-the-clock opioid pain medicine. This is extremely important because patients who are opioid-tolerant are more resistant to the dangerous side effects of opioid pain medicines than patients who only take these medicines occasionally. For patients who are not opioid-tolerant, the amount of fentanyl in one fentanyl patch of the lowest strength is large enough to cause dangerous side effects, such as respiratory depression (severe trouble breathing or very slow or shallow breathing), and potentially, death.

The FDA highlighted the following important safety information on the fentanyl skin patch:

- **The fentanyl patch should only be used by patients who are opioid-tolerant and have chronic pain that is not well controlled with other pain medicines.** They are not to be used to treat sudden, occasional, or mild pain, or pain after surgery.
- **Healthcare professionals who prescribe, and patients who use, the fentanyl patch should be aware of the signs of fentanyl overdose, including the following:** Trouble breathing or slow or shallow breathing; slow heartbeat; severe sleepiness; cold, clammy skin; trouble walking or talking, or; feeling faint, dizzy, or confused. If these signs occur, patients or their caregivers should get medical attention immediately.
- **Patients with a prescription for the fentanyl patch should tell their doctor about all the medicines that they take.** Some medicines may interact with fentanyl causing dangerously high fentanyl blood levels and life-threatening breathing problems.
- **Patients and their caregivers should be told how to use the fentanyl patch.** This important information, including instructions on how often to apply the patch, reapplying a patch that has fallen off, replacing a patch, and disposing of the patch is provided in the patient information that comes with the fentanyl patch.
- **Heat may increase the amount of fentanyl that reaches the blood and can cause life-threatening breathing problems and death.**
  - Patients should not use heat sources such as heating pads, electric blankets, saunas, or heated waterbeds; or take hot baths or sun bathe while wearing a patch.
  - A patient or caregiver should call the patient's doctor right away if the patient has a fever higher than 102°F while wearing a patch.

## **Nursing Home Guidance Update** By Doug Englebort, R.Ph.

**The following is a conversation overheard in a nursing home between a nurse and the administrator: The physician started Mrs. J. on a hypnotic medication for chronic insomnia. “We have to make sure the consultant pharmacist requests a dose reduction within three months so we do not get cited, otherwise we should be all right using the medication.”**

It seems like a lot of focus for sleep medications is on the dose reduction, when in fact, most of the attention should be on the reasons the medication was started. When sleep medications are being used, and it is early in the treatment phase, surveyors should make sure they determine if the facility fully assessed the reason the resident was not sleeping. For example, was the insomnia due to loud noises, reflux disease, pain, etc.? These and other medical and/or environmental issues can dramatically affect the quality of sleep. They should be assessed and ruled out. If this has not been done, then adequate indications for sleep medication have not been established, and the medication may be unnecessary.

The dose of the medication may also be a concern for elderly individuals. Typically, lower doses should be given at the beginning to decrease any potential adverse effects of the medication.

In addition to indication and dose, appropriate monitoring should be initiated to look at effectiveness and adverse effects. The facility should have steps in place to monitor the sleep of a resident who is put on sleep medication. If the medication is not working, then it should be discontinued or adjusted. If the medication is causing side effects, it should be discontinued.

In the above conversation, the assumption could be that the physician diagnosed chronic insomnia, and therefore, there are adequate indications for use. In actuality, it could be that the sleep medication was prescribed by the on-call physician due to a call from staff the night before, and not based on any assessment. In this case the label of chronic insomnia may not be supported, and therefore, the concern should be more than the three-month reminder to complete a dose reduction. The best time to limit the sleeping medication use is at the point of initiation of the medication. Once the medication has been used for several weeks or months, it becomes more difficult to eliminate.

## **Consultant Corner** By Doug Englebort, R.Ph.

### **1. When do eye drops expire?**

It depends on the eye drop product you are using. In some cases, the eye drops are single-use unit-dose products that often have no preservatives. If these eye drops are opened, they typically have a short shelf life and may need to be disposed of within hours. Therefore, if administration of the eye drop must be delayed for some reason, then there should be a process in place to dispose of the eye drop when appropriate.

In other cases, the eye drops that are being used are compounded products that may have a short shelf life as low as 24-72 hours. These eye drops may not be available commercially, or are not available due to drug shortages. In these situations, pharmacists may make the eye drops. This practice is more common in hospitals with eye clinics or eye surgery centers. The eye drop expiration date in these cases will be based on studies and preparation techniques. In these cases, the eye drops will often expire in 30 days or less. Compounding pharmacists will label the eye drop with the appropriate storage requirements and expiration date.

In most cases, however, the eye drops that most surveyors and facilities will see are multiple-dose bottles of eye drops. Some of these eye drops will have decreased shelf life once opened. For example, Xalatan when unopened must be stored in a refrigerator. Once Xalatan is open, it can be stored at room temperature for six weeks. Most eye drops, however, are not like Xalatan and are stored at room temperature at all times; and can be used up until the stamped expiration date provided by the manufacturer. The package inserts will contain the manufacturer's requirements for storage of eye drops. Those storage requirements need to be maintained in order for the eye drops integrity to be maintained. For some facilities, due to infection control concerns, eye drops, even in multi-dose bottles will be destroyed in 30 to 60 days. Those policies are acceptable.