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Ask The Pharmacist

To suggest a topic, send an email to: AskThePharmacist@cvty.us.com

Is Opana® ER being pulled from the market?

Yes it is, but while Opana ER will no longer be manufactured or available starting next month, it is interesting to note that this is not due to a recall. Rather, the U.S. Food and Drug Administration (FDA) asked Endo, the makers of Opana ER, to stop selling the drug. The request came this June following increasing evidence that the FDA claimed tipped the scales for Opana ER where the potential benefit from use of this particular drug no longer outweighed the risk of harm or abuse. Endo agreed to voluntarily remove Opana ER from the market but maintains that the drug is safe and beneficial when used as intended and according to prescribing information. Opana ER is a long-acting opioid analgesic indicated for the management of severe pain where alternative treatment options are inadequate.

While Opana ER was reformulated in 2012 with properties to help discourage crushing and defeat of the extended-release formulation for abuse through nasal (aka, snorting) or injectable routes, it was never considered to meet with the FDA's requirements for granting "abuse-deterrent labeling" approval, thus Opana ER was not recognized as an abuse-deterrent opioid by the FDA. Further, the FDA recently cited research[1] that showed when the drug was reformulated, a shift was seen from nasal abuse to an increase in abuse through the injectable route. More information related to the FDA's guidance for the industry related to opioids along with a current list of opioids with FDA-approved abuse-deterrent labeling can be found on their website.

What is the timeline for removal?

Endo has announced that shipments of oxymorphone HCl extended-release (Opana ER) will end on September 1, 2017. Shipments will continue in the mean time to allow those currently taking Opana ER time to speak with their health care provider about other treatment options such as a change to a different medication. As with all opioids, Opana ER should not be stopped abruptly as this can lead to unwanted effects such as withdrawal symptoms. Instead, the medication should be tapered down slowly, depending on the dose and taking into account what, if any, planned replacement medication the injured worker may receive.

Alternative pain treatments and withdrawal medications

In some cases, the health care team may feel it is most appropriate to discontinue Opana ER and opioid therapy. This will typically involve a tapering schedule where the injured worker would receive decreasing doses of the medication over a period of a few days to several weeks depending on the patient's current opioid dose, duration of treatment, and comorbid conditions. Several medications have been shown to help diminish the typical symptoms that may accompany opioid withdrawal, and coverage may be appropriate for short-term aid in weaning management. For example, the alpha-2 agonist clonidine may help with associated increases in blood pressure or heart rate, nausea, cramps, and/or sweating. Antihistamines or trazodone may be used to help with insomnia and restlessness. Other options might include non-steroidal anti-inflamitory drugs (NSAIDs) for muscle aches, dicyclomine for abdominal cramps, and Pepto-Bismol® for diarrhea.

If continuation of opioid therapy is considered most appropriate, a switch to a different opioid will likely be requested. Although the drug formulary or client drug list may vary, in general the following long-acting or extended-release opioid medications would be considered first-line alternatives for Opana ER: morphine sulfate ER tablets (generic for MS Contin®) or tramadol ER tablets (generic for Ultram ER®). Other options may be available depending on the injured worker's specific drug history or treatment needs.

A number of non-opioid alternatives are also available for treating pain. A provider may consider a switch to analgesics such as an NSAID (e.g., ibuprofen, naproxen, celecoxib), acetaminophen, or Aspirin. So-called "adjuvant analgesics," or drugs that may not have direct pain-relieving properties but that have been shown to be beneficial for relief of specific pain problems or as part of an overall pain management plan, may also be useful treatment options. Examples include use of an anticonvulsant

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(e.g., gabapentin), antidepressant (e.g., duloxetine), topical (e.g., capsaicin cream), or corticosteroid (e.g., dexamethasone). Non-pharmacological treatments such as cognitive behavioral therapy may also be considered.

What steps should you take today?

If you know an injured worker is currently receiving Opana ER, an outreach should be made, if possible, to advise this person that the medication will no longer be available and to help coordinate a change in treatment with that injured worker's medical provider. The injured worker should be encouraged to speak with his or her prescriber as soon as possible to avoid unnecessary interruptions in care, and consideration of each individual's medication history and available drug formulary options can help to guide decisions related to alternative drug treatments that follow first-line or evidence-based recommendations. For example, working with First Script to ensure that any new drug selections follow first-line or qualifying formulary options can help to avoid frustrations throughout the drug dispensing process for all involved (i.e., injured worker, prescriber, adjuster, etc.). If treatment decisions involve discontinuing the use of opioid medication, allowances should be made to accommodate a weaning or tapering schedule of the current opioid, as well as for the potential provision of medications known to help with withdrawal symptom management.

In any case, the individual patient's characteristics must be considered and weighed carefully against his or her drug history, disease state, and comorbid conditions and evaluated as a complete picture of care. Decisions for managing drug treatment should not be made in a vacuum, so proper coordination with the injured worker's health care team and First Script resources is essential for ensuring best outcomes. If you have any questions related to drug formulary options or for further guidance on the discontinuation of Opana ER, please contact your Account Manager. You may also send your questions to our team of clinical pharmacists at askthepharmacist@cvty.com.

Reference: https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM545760.pdf

Drug of the Month

Embeda®

Embeda is a combination opioid agonist/opioid antagonist product that was approved by the FDA in August of 2009 for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Embeda extended-release capsules contain morphine sulfate combined with naltrexone in an effort to deter abuse of the opioid component. Embeda was the first extended-release morphine product designed to deter oral or intranasal abuse through crushing and was also granted FDA-approval for its abuse-deterrent labeling.

Pfizer, the drug's manufacturer, indicates that the product's abuse-deterrent properties have been demonstrated in a handful of laboratory studies and clinical trials. Essentially, if Embeda is taken according to the directions for use, the patient experiences only the effects of extended-release morphine. However, if the product is manipulated through crushing, dissolving, or chewing, the sequestered naltrexone (the antagonist) will be released and will counteract the effects of morphine. The release of naltrexone may also precipitate withdrawal in patients who are dependent on opioids.

The intended dosing for Embeda is for oral use on a scheduled basis every 24 hours in patients who are considered opioid tolerant (i.e., taking at least 60 mg oral morphine (or equivalent) per day for one week or longer). The capsules are to be swallowed intact, or they may be opened with the pellets sprinkled in applesauce and immediately swallowed without chewing. Embeda is available in six strengths ranging from 20 mg morphine/0.8 mg naltrexone to 100 mg morphine/4 mg naltrexone, and the lowest effective dose should be used for the shortest duration to minimize risk.

Embeda is a Schedule II Controlled Substance, and although it possesses abuse-deterrent properties, abuse is still possible. Due to these risks along with the associated increased potential risk of overdose with extended-release products, providers are encouraged to assess the patient's risk of addiction, abuse, or misuse prior to prescribing Embeda and regularly thereafter. Today, the impact of abuse-deterrent formulations on prescription opioid abuse is difficult to validate as long-term post-marketing data are lacking. While such products represent a viable additional tool for the prevention of prescription drug abuse, they are not fool-proof, and provider vigilance and the application of evidence-based treatment best practices remain essential. For all of these reasons, it is recommended that the use of Embeda be reserved for individuals for whom alternative therapies such as non-opioid analgesics or short-acting opioids are not tolerated or are insufficient to provide adequate pain relief, and for whom first-line extended-release opioids, such as generic morphine sulfate ER tablets or tramadol ER tablets, have been tried and failed or are not tolerated.

References:
http://www.accessdata.fda.gov/scripts/cder/drugsatfda/
www.pfizer.com