



STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene

201 W. Preston Street • Baltimore, Maryland 21201

Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – Joshua M. Sharfstein, M.D., Secretary

May 14, 2014

Dear Colleague,

In response to public health concerns following the recent FDA approval and market release of Zohydro ER, we would like to provide clinicians with the necessary tools to make appropriate prescribing decisions in treating patients with chronic pain.

Zohydro ER is a single entity hydrocodone tablet (it does not contain acetaminophen, ibuprofen or aspirin). It is available in six different strengths from 10 mg to 50 mg and is labeled to be prescribed no more frequently than every 12 hours. This medication may represent a reasonable alternative for some patients who suffer from intractable, chronic pain. It does not pose the same risk to the liver of hydrocodone formulations that contain acetaminophen.

However, several properties of the medication raise concern and require prescribing with a heightened level of caution. First, the tablets were not designed to be tamper-resistant, so if the extended release tablets are crushed or chewed, this could lead to more immediate and unpredictable release of the opiate into the patient's system. Second, unlike a number of oxycodone-containing medications on the market, Zohydro ER is not an abuse deterrent formulation.¹ These limitations are significant, because prescription drug abuse and overdose is a serious and deadly problem in Maryland and the nation.²

In its press release on October 25, 2013 regarding its approval of Zohydro ER, FDA stated because of the greater risks of overdose and death with ER/LA opioid formulations, Zohydro ER should be reserved for use in patients for whom alternative treatment options are ineffective or not tolerated. Zohydro ER is not approved for as needed pain relief.³

For clinicians who prescribe Zohydro ER as well as other opioids for pain management there are several basic good practices to keep in mind:⁴

- Review all medications with the patient and pharmacy as a check for drug interactions
- Use the lowest effective dose to prevent adverse drug reactions
- Obtain signed consent for communication with all other providers/prescribers and pharmacies
- Collect and review medical records, including recent imaging studies, preferably from the original source, to confirm prior diagnoses and medical regimens
- Appropriately document patient interactions, expectations and outcome goals
- Keep a signed contract which explains expectations of opiate use
- Use urine drug screening, random or scheduled
- Consider ancillary therapies and referrals for specialty care such as physical therapy and referral to orthopedics and pain management clinics
- Screen the patient for mental health or addiction issues

¹<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM336475.pdf>

²<http://www.cdc.gov/media/dpk/2013/dpk-2013-review.html>

³ <http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm372287.htm>

⁴ Mathias, A. Assuring a Safe Environment for CDS Prescribing. Maryland Board of Physicians Newsletter: Winter 2012.

⁵<http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm330614.htm>

On the attached newsletter, page 2 and 3, is a discussion of appropriate prescribing practices for pain from the Maryland Board of Physicians.

If a patient is identified with potential mental health or addiction issues, refer for appropriate treatment as soon as possible. You can find more information about available treatment resources in your community by visiting the following websites.

- Alcohol and Drug Abuse Administration: <http://adaa.dhmf.maryland.gov/SitePages/Need-Help.aspx>
- Mental Hygiene Administration: <http://www.dhmf.maryland.gov/mha/SitePages/help.aspx>

Furthermore, the FDA recommends all clinicians prescribing opioids follow these steps.^{3,5}

- Know the content of the most current opioid drug labels
- Educate patients about the appropriate use of opioids, their potential risks, and proper disposal techniques
- Visit the FDA's Risk Evaluation and Modification System (REMS) website on up-to-date information on specific opiate medication-associated risks:
<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111350.htm>

Specifically for Zohydro ER, FDA recommends that clinicians document that other pain medications have failed. They also caution against use in elderly and debilitated patients and those with respiratory depression or hypercarbia.

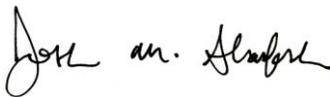
We also strongly recommend that all clinicians prescribing opioid medications regularly query the Maryland Prescription Drug Monitoring Program, otherwise known as the PDMP, for information about whether their patients are receiving medications from other sources. This free service allows healthcare providers to access prescription data and more safely manage their patients' use of controlled substances. Please visit the following website for more information and to register: <http://adaa.dhmf.maryland.gov/PDMP/SitePages/Home.aspx>

Thank you for your attention to this matter.

Sincerely,



Mona K. Gahunia, D.O.
Chief Medical Officer



Joshua M. Sharfstein, M.D.
Secretary

Attachment: Maryland Board of Physicians Newsletter, Winter 2012

¹<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM336475.pdf>

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