Zyprexa Relprevv Receives Attention After 2 Unexplained Deaths

The U.S. Food and Drug Administration (FDA) is investigating two unexplained deaths in patients who received an intramuscular injection of the antipsychotic drug Zyprexa® Relprevv™ (olanzapine pamoate). The patients died 3 to 4 days after receiving an appropriate dose of the drug, well after the 3-hour postinjection monitoring period required under the Zyprexa Relprevv Risk Evaluation and Mitigation Strategy (REMS). Both patients were found to have very high olanzapine blood levels after death. High doses of olanzapine can cause delirium, cardiopulmonary arrest, cardiac arrhythmias, and reduced level of consciousness ranging from sedation to coma.

The FDA is providing this information to health care professionals while it continues its investigation. If therapy with Zyprexa Relprevv is started or continued in patients, health care professionals should follow the REMS requirements and drug label recommendations. Patients and caregivers should talk to their health care professional about any questions or concerns.

Under the REMS, patients are required to receive the Zyprexa Relprevv injection at a REMS-certified health care facility, to be continuously monitored at the facility for at least 3 hours following an injection, and to be accompanied home from the facility. The Zyprexa Relprevv label contains warnings about the risk of postinjection delirium sedation syndrome (PDSS), a serious condition in which the drug enters the blood too fast following an intramuscular injection, causing greatly elevated blood levels with marked sedation (possibly including coma) and/or delirium. In the clinical trials supporting the approval of Zyprexa Relprevv, cases of PDSS were observed within 3 hours after administration of Zyprexa Relprevv, but there were no deaths due to PDSS. These two patients died 3 to 4 days after receiving an appropriate dose of the drug, and it is not clear whether they died from PDSS.

New Choice for Opioid Dependence Treatment Approved

Pharmaceutical company Orexo U.S., Inc. announced that it has received approval from the U.S. Food and Drug Administration for Zubsolv® (buprenorphine and naloxone) sublingual tablets (CIII). Zubsolv is indicated for the maintenance treatment of opioid dependence and should be used as part of a complete treatment plan to include counseling and psychosocial support. Zubsolv is a once-daily, sublingual tablet with higher bioavailability, a fast dissolve time, smaller tablet size, and a new menthol flavor.

Zubsolv sublingual tablets deliver more active ingredient to the bloodstream, allowing patients to use a lower strength, thereby reducing the amount of available drug for potential misuse and diversion. In addition, Zubsolv is the only opioid dependence treatment option that is available in the highest level of child resistant unit dose F1 packaging, thereby reducing the chance of unintended pediatric exposure. Furthermore, the naloxone component of Zubsolv reduces the potential for intravenous misuse and diversion.

At this time, the FDA is continuing to evaluate these deaths and will provide an update when more information is available.

Do You Have Any Product News to Share?
JPN would like to hear about it.

Please forward pertinent information to:
Journal of Psychosocial Nursing & Mental Health Services
6900 Grove Road, Thorofare, NJ 08086
Fax: (856) 848-6091
E-mail (preferred): jpn@slackinc.com


doi:10.3928/02793695-20130709-89