

U.S. Food and Drug Administration

FDA Talk Paper

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FDA STRENGTHENS WARNINGS FOR DROPERIDOL

FDA has strengthened the warnings and precautions sections in the labeling for droperidol, a tranquilizer used most often as a premedication for anesthesia, as treatment for nausea after anesthesia, and for sedation of agitated patients. Droperidol has been associated with fatal cardiac arrhythmias.

Specific changes to the droperidol labeling include a "black box" warning, the most serious warning for a FDA-approved drug. The new warning is intended to increase the physician's focus on the potential for cardiac arrhythmias during drug administration, and to consider use of alternative medications for patients at high risk for cardiac arrhythmias.

Droperidol currently carries a warning about cases of sudden death at high doses (greater than 25 mg) in patients at risk for cardiac arrhythmias. Recent research has shown QT prolongation (delayed recharging of the heart between beats) within minutes after injection of a dose of droperidol at the upper end of the labeled dose range. Prolonged QT is dangerous because it can cause a potentially fatal heart arrhythmia known as torsades de pointes (TdP).

In the last year, there have been reports of TdP within or below the currently labeled dose range. There have also been reports of sudden death or other serious cardiac adverse events.

FDA will continue to monitor the postmarketing safety data for droperidol to determine if further action is needed.

The manufacturer, Akorn Pharmaceuticals, is sending a "Dear Healthcare Professional" letter to physicians, pharmacists, and other healthcare professionals in the U.S. The letter explains the black box warnings and highlights the potential for QT prolongation or torsades when this drug is administered.

For more information, patients and healthcare providers can call Akorn Pharmaceuticals at 1-888-519-8384.

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Dear Health Care Professional letter, Dec. 4, 2001

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