

WY-DUR
Wyoming Drug Utilization Review Board
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Dear Doctor:

Johnson and Johnson and the Food and Drug Administration have recently announced the addition of cardiovascular warnings to the label of haloperidol. We are providing this information as an educational service to those who have prescribed haloperidol to Medicaid recipients in the last six months.

The updated haloperidol label includes warnings regarding the risk of Torsades de Pointes and QT prolongation in patients receiving haloperidol. This risk is especially high when given at doses higher than recommended or when administered intravenously.

Recommended dose

It is difficult to find a published maximum dose for haloperidol. Micromedex lists the recommended dose as three to five milligrams three times daily for schizophrenia, Gilles de la Tourettes's and panic disorder. Although rare, some patients may safely tolerate up to 60 mg per day. Usual doses are generally less than 10 mg per day. When doses above 10 mg per day are used, patients are typically tapered from a lower initial dose to the required maintenance dose.

Intravenous use

The injectable forms of haloperidol have been approved for intramuscular administration only. However, there is evidence that the medication is commonly given "off-label" intravenously, especially in the emergency room setting. The FDA reports that there are at least 28 cases of adverse cardiovascular events in the medical literature, some with fatal outcome associated with intravenous use. At the request of the Italian Drug Agency, Johnson and Johnson conducted a search of their Benefit Risk Management worldwide safety database for QT prolongation. The reports identified 229 reports of QT prolongation and seventy-three cases of Torsades de Point. Eleven cases of Torsades de Pointes were fatal, eight of which involved intravenous administration of haloperidol at various doses. Case-control studies have shown a dose response relationship between intravenous dose and occurrence of Torsades de Pointes.

Predisposing factors

There have been cases of adverse cardiovascular events, including sudden death, in those without predisposing factors. However, particular caution is advised in using any formulation of haloperidol in those who have other QT prolonging conditions, underlying cardiac abnormalities, hypothyroidism, or are taking other drugs known to prolong the QT interval.

Monitoring

ECG monitoring is recommended if haloperidol is given intravenously.

Thank you for continuing to care for Wyoming Medicaid patients.

Sincerely,



James Robinett, D.O.

References:

1. FDA Information for Healthcare Professionals, Haloperidol. <http://www.fda.gov/cder/drug/InfoSheets/HCP/haloperidol.htm> accessed October 3, 2007.
2. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Micromedex. Updated periodically.