Ditropan Has Been Linked to Hallucinations

On April 9, 2007, the FDA released documents stating the Johnson & Johnson's drug Ditropan for overactive bladders needs stronger warnings about the threat of hallucinations and other related problems in children and older patients. The Food & Drug Administration originally approved Ditropan (generic: Oybutynin) in June 1999.

To date, the label for Ditropan already lists insomnia, nervousness, confusion and other central nervous system risks, but staff reviewers said more explicit cautions are needed. The FDA's gatherings state that, the labeling for Ditropan should point out that the drug can cause such problems and that the risks have been reported in patients taking the drug. It should furthermore call on doctors to monitor for symptoms, they wrote in a memo dated March 2007.

An FDA team evaluated 202 reports of central nervous system side effects in Ditropan patients; 37 in those 17 and younger and 143 in adults; no age was reported in 22 cases. Of those 202 reports mentioned hallucinations in 27% of the pediatric cases and in 25% of those aged 60 and older. Hallucinations were reported in 11% of cases for adults aged 17 to 59.