

ARTICLE IN BRIEF

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Pimavanserin, Adverse Events

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mortality. “Even pimavanserin has this black box warning.”

To date, he noted, no clinical studies have demonstrated an increased mortality in pimavanserin patients related to the medication.

“The FDA’s FAERS database is unmonitored, and there can be multiple reports of a single patient from different resources, such as a family member, physician, pharmacist, etc.”

Moreover, pimavanserin is prescribed through a specialty pharmacy which has increased patient contacts even after the patient discontinues the drug, he added. “They have to report any cases of death,

which is not true of medications prescribed through neighborhood pharmacies.”

Mortality rates from Medicare database show mortality rates (per 100 patient years) of 7.3 for PD patients without psychosis, and 28 for PD patients with psychosis, for atypicals like quetiapine, with a rate of 18.6, and olanzapine, at 29.3, while post marketing data for pimavanserin is about 12.4, he said.

“In my personal experience with pimavanserin, it is effective in a majority of PD psychosis patients. We need to further study the reports of increased mortality, but in a scientific manner.”

Joseph Jankovic, MD, FAAN, the Distinguished Chair in Movement Disorders and director of the Parkinson’s Disease Center at Baylor College of

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Medicine in Houston, told *Neurology Today* that his patients have also responded well to treatment.

“While not all patients are completely satisfied, many of my patients have experienced marked improvement

in their visual hallucinations, paranoia, and other psychotic symptoms,” he said. “I suspect that the death rates in elderly patients with advanced PD and psychosis are higher than in a control population without these problems, so it’s not surprising to see deaths in such patients who are taking pimavanserin, but the cause-effect relationship has not been established.”

Nevertheless, he advised physicians to closely follow patients, especially if they have other medical problems or are taking concomitant medications that could increase their risk of drug-related complications.

“Long-term monitoring, and continuous and vigorous data collection, are needed before any definite conclusions can be made. For the time being, at least



DR. CYNTHIA COMELLA:
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in my patients, I believe the benefits outweigh the risks.”

Cynthia Comella, MD, FAAN, professor of neurology at Rush University Medical Center’s Parkinson’s Disease and Movement Disorders Section in Chicago, said she is not going to change how she treats her PD patients.

“I think it is too soon to be concerned specifically about this drug. We don’t have enough data — the extent of these adverse events or how they might compare with other atypical agents,” she told *Neurology Today*. “I feel that we need to be cautious with all of these drugs. I especially have concerns prescribing them in elderly patients because they are more fragile and usually have additional disorders and health conditions.” •

DISCLOSURES

Drs. Jankovic and Comella reported no related conflicts of interest. Dr. Pahwa has received consulting fees from Abbvie, Acadia, Acorda, Adamas, Cynapsus, Global Kinetics, Ionis, Lundbeck, Neurocrine, St Jude Medical, Teva Neuroscience, UCB, and US World Meds. He has received research grants from Acorda, Adamas, Avid, Boston Scientific, Cala Health, Cynapsus, Kyowa, National Parkinson Foundation, NIH/NINDS, Parkinson Study Group, Pfizer, and US WorldMeds.

LINK UP FOR MORE INFORMATION:

- CNN Investigates: FDA worried drug was risky; now reports of deaths spark concern: <http://bit.ly/Pimavanserin>
- ISMP Report: Safety signals for two novel drugs: <http://bit.ly/ISMP-report>