

- This multicenter, open-label, phase 3b study, which was conducted in private practices, hospitals, and a clinical trial site in Germany, evaluated the effects of stable doses of tapentadol prolonged release (PR) on driving ability in patients who had completed previous tapentadol PR trials for severe low back or osteoarthritis pain using a global judgment based on a computerized test battery.
- In this study, pain scores remained unchanged from enrollment to final visit (mean [standard deviation] change, -0.2 [1.0]), and two adverse events (considered unrelated to study drug) were reported.
- Of the 35 patients who completed all 6 tests, 65.7% (23/35) were classified as fit to drive based on the global judgment of driving-specific ability, and total daily tapentadol PR doses had no effect on global judgment of driving ability.
- These results suggest that most patients receiving stable doses of tapentadol PR (a μ -opioid receptor agonist and noradrenaline re-uptake inhibitor) for severe, chronic pain will be able to drive, which is consistent with results of previous studies that have shown that patients on stable doses of opioids are able to drive safely.

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