Abstract

Objective:
To evaluate tolerability, safety, and quality-of-life outcomes in non-opioid-pretreated patients with severe chronic low back pain with a neuropathic component receiving tapentadol PR vs. oxycodone/naloxone PR.

Methods:
Eligible patients (average pain intensity [numerical rating scale] ≥ 6; painDETECT positive/unclear ratings) were randomized to twice-daily tapentadol PR 50 mg or oxycodone/naloxone PR 10 mg/5 mg. After a 21-day titration (maximum twice-daily doses: tapentadol PR 250 mg, or oxycodone/naloxone PR 40 mg/20 mg plus oxycodone PR 10 mg), target doses were continued for 9 weeks. Change in the Patient Assessment of Constipation Symptoms (PAC-SYM) total score from baseline to final evaluation was a primary endpoint.

Results:
For the primary tolerability-related endpoint, the 97.5% exact repeated confidence interval for tapentadol PR minus oxycodone/naloxone PR for the PAC-SYM total score was [-0.259, 0.121], showing noninferiority (upper limit < 0.7). Incidences of constipation and vomiting were significantly lower with tapentadol PR than oxycodone/naloxone PR (P ≤ 0.045). Confirmatory superiority based on formal noninferiority was shown for the primary effectiveness endpoint (change from baseline to final evaluation in pain intensity) for tapentadol PR vs. oxycodone/naloxone PR (presented separately). Improvements in the Short Form-12 physical component summary and EuroQol-5 Dimension health status index and health state assessment were significantly greater with tapentadol PR vs. oxycodone/naloxone PR (P ≤ 0.024).

Conclusions:
Tapentadol PR had a minimal impact on bowel function (noninferior to oxycodone/naloxone PR) and, along with superior effectiveness (presented separately), was associated with significantly lower incidences of constipation and vomiting and significant improvements in quality-of-life measures vs. oxycodone/naloxone PR.
Practical Considerations for the Use of Tapentadol Prolonged Release for the Management of Severe Chronic Pain

Full-text Article · Aug 2014 · Clinical Therapeutics

Manuel J. Sánchez del Águila, Michael Schenk, Kai-Uwe Kern, Ilona Steigerwald

Tapentadol hydrochloride: A next-generation, centrally acting analgesic with two mechanisms of action in a single molecule

Article · Jul 2009 · Drugs of today (Barcelona, Spain: 1998)

Thomas M Tzschentke, Ulrich Jahnel, Babette Kogel, Regina Kleinert

Prevalence of chronic pain with neuropathic characteristics in the general population. Pain 136: 380-387

Full-text Article · Jul 2008 · Pain

Didier Bouhassira, Michel Lantéri-Minet, Nadine Attal, Chantal Touboul

The Prevalence, Severity, and Impact of Opioid-Induced Bowel Dysfunction: Results of a US and European Patient Survey (PROBE 1)

Article · Sep 2008 · Pain Medicine

Timothy J Bell, Sunil J Panchal, Christine Maskowski, Russell Williamson

Psychometric Validation of a Constipation Symptom Assessment Questionnaire

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L. Frank, L. Kleinman, C. Farup, L.


Article · Jan 2005 · Pain

Eija Kalso, Jayne E Edwards, R Andrew Moore, Henry J McQuay
The burden of neuropathic pain: A systematic review and meta-analysis of health utilities

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Alissa H Doth Per T Hansson Mark P Jensen Rod S Taylor

Nausea and Vomiting Side Effects with Opioid Analgesics during Treatment of Chronic Pain: Mechanisms, Implications, and Management Options

Full-text Article · Apr 2009 · Pain Medicine
Frank Porreca Michael H Ossipov

Effectiveness and safety of tapentadol prolonged release for severe, chronic low back pain with or without a neuropathic pain component: Results of an open-label, phase 3b study

Article · Mar 2012 · Current Medical Research and Opinion
Ilona Steigerwald Matthias Müller Anthony Davies Hans G Kress

Neuropathic pain: Diagnosis, pathophysiological mechanisms, and treatment

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Ralf Baron Andreas Binder Gunnar Wasner

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