Dokumenttyp: journal article

Autor(en) des Beitrags:
Oertel, Wolfgang H; Hallström, Yngve; Saletu-Zyhlarz, Gerda M; Hopp, Michael; Bosse, Björn; Trenkwalder, Claudia; RELOXYN Study Group; Högl, B; Röper, C; Saletu-Zyhlarz, G; Behrens, S; Bene?, H; Bergtholdt, B; Bitter, R; Bodenschatz, R; Böhringer, J; Boldt, H-J; Braune, S; Donat, P; Fietze, I; Franz, P; Geisler, P; Gertz, H-J; Gestewitz, B; Haan, J; Happe, S; Henin, H; Hornyak, M; Hufnagel, A; Kallmann, B-A; Karlbauer, G; Kassubek, J; Klein, M; Koppai-Reiner, J; Lang, M; Leibinger, R; Lüer, W; Lünser, W; Mahler, A; Mattern, W; Mayer, G; Molt, W; Oertel, W; Peglau, I; Peltz, J; Rütgers, E; Sallach, K; Schöll, I; Schulze, A; Schumann, V; Siefjediers, V; Siever, A; Sigel, K-O; Simonow, A; Sixel-Döring, F; Sloksnat, R; Sommer, H; Springub, J; Spieker, T; Steinwachs, K-C; Stiasny-Kolster, K; Stierstorfer, A; Storch, A; Tinschert, K; Trenkwalder, C; Veit, B; Warmuth, R; Young, P; Zuchner, D; García-Borreguero, D; Irano de Riquer, A; Martinez Rodriguez, JE; Puertas, FJ; Romero Santo-Tomás, O; Grote, L; Hallström, Y; Markström, A

Titel des Beitrags:
Sleep and Quality of Life Under Prolonged Release Oxycodone/Naloxone for Severe Restless Legs Syndrome: An Analysis of Secondary Efficacy Variables of a Double-Blind, Randomized, Placebo-Controlled Study with an Open-Label Extension.

Abstract:
The aim was to assess the effects of prolonged release oxycodone/naloxone (OXN PR) on sleep and quality of life (QoL) in patients with severe restless legs syndrome (RLS) refractory to first-line dopaminergic RLS treatment.
randomized, double-blind, placebo-controlled study with subsequent 40-week, open-label extension were analyzed. Instruments included the Medical Outcomes Study (MOS) sleep scale, RLS-6 rating scale, and RLS-QoL questionnaire. The full analysis population included 132 OXN PR and 144 placebo patients. After 12 treatment weeks, improvements in the MOS domains 'sleep disturbance' [-18.6; 95 % confidence interval (CI) -24.4 to -12.9; p< 0.0001], 'sleep adequacy' (14.9; 95 % CI 7.9-21.9; p< 0.0001), and 'sleep quantity' (0.77 h; 95 % CI 0.43-1.11; p< 0.0001) were significantly greater under OXN PR than under placebo. OXN PR also reduced symptom severity (when falling asleep and during the night) and daytime tiredness, and increased sleep satisfaction to a significantly greater extent than placebo (all p< 0.001; RLS-6). QoL improved in both treatment arms, with a significant difference of -9.02 (95 % CI -12.85 to -5.19; p< 0.001) in the mean sum score in favor of OXN PR. All sleep and QoL aspects also improved under 40 weeks of open-label OXN PR treatment. OXN PR improved RLS symptom severity and sleep quantity and adequacy, resulting in greater sleep satisfaction, less daytime tiredness, and improved QoL. In appropriate patients, OXN PR should be considered as an alternative treatment option for severe RLS that cannot be controlled by first-line dopaminergic medications. ClinicalTrials.gov (NCT01112644) and EudraCT (2009-011107-23).