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A multicentre, open-label, follow-on study to assess the long-term maintenance of effect, tolerance and safety of THC/CBD oromucosal spray in the management of neuropathic pain.

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Abstract

Peripheral neuropathic pain (PNP) poses a significant clinical challenge. The long-term efficacy of delta-9-tetrahydrocannabinol (THC)/cannabidiol (CBD) oromucosal spray was investigated in this 38-week open-label extension study. In total, 380 patients with PNP associated with diabetes or allodynia entered this study from two parent randomised, controlled trials. Patients received THC/CBD spray for a further 38 weeks in addition to their current analgesic therapy. Neuropathic pain severity was the primary efficacy measure using a pain 0-10 numerical rating scale (NRS). Additional efficacy, safety and tolerability outcomes were also investigated. In total, 234 patients completed the study (62 %). The pain NRS showed a decrease in score over time in patients from a mean of 6.9 points (baseline in the parent studies) to a mean of 4.2 points (end of open-label follow-up). The proportion of patients who reported at least a clinically relevant 30 % improvement in pain continued to increase with time (up to 9 months); at least half of all patients reported a 30 % improvement at all time points. Improvements were observed for all secondary efficacy outcomes, including sleep quality 0-10 NRS scores, neuropathic pain scale scores, subject global impression of change and EQ-5D questionnaire scores. THC/CBD spray was well tolerated for the study duration and patients did not seek to increase their dose with time, with no new safety concerns arising from long-term use. In this previously difficult to manage patient population, THC/CBD spray was beneficial for the majority of patients with PNP associated with diabetes or allodynia.

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