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TOLERABILITY AND SAFETY OF AS-NEEDED NALMEFENE IN THE TREATMENT OF ALCOHOL DEPENDENCE: RESULTS FROM THE PHASE 3 PROGRAMME

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Introduction: The phase 3 programme investigating nalmefene for reduction of alcohol consumption in alcohol dependent patients comprised two 6-month studies (ESENSE1 and 2) and one 12-month study (SENSE), conducted in 19 European countries.

Objectives: To investigate the tolerability and safety of as-needed use of 18 mg nalmefene.

Methods: 1997 patients with a diagnosis of alcohol dependence were recruited. Adverse events (AEs) and other safety variables were recorded.

Results: 797 patients in the placebo group and 1144 patients in the nalmefene group received study medication; patients took study medication on 62% and 51% of the days, respectively. The incidence of AEs was high in both the placebo and the nalmefene group (62.7% and 74.7%, respectively), and was not dependent on the drinking risk level at baseline. While mostly mild or moderate, these AEs did lead to dropout in some patients: 47 patients (6%) in the placebo group and 149 patients (13%) in the nalmefene group. Patients continuing in the studies seemed to develop tolerance with time for the most frequent AEs. Median time to event and median duration of these AEs were generally shorter for nalmefene than for placebo (many started after 1st dose). 35 patients (4.4%) in the placebo group and 57 patients (5.0%) in the nalmefene group had serious adverse events (SAEs). The majority of SAEs were not related to study medication and no apparent trends with respect to overall incidence or distribution across organ systems were noted.

Conclusion: Nalmefene was well-tolerated and no major safety issues were identified.

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