VI.2 Elements for a public summary

VI.2.1 Overview of disease epidemiology

Alcohol dependence:

In the United Kingdom (UK), 51% of English pupils (age 11 to 15) in 2008 reported ever having an alcoholic drink, an increase from 2003 when the figure was 39%. About 48-49% of drinking occasions lead to intoxication in the UK among 15-16 year olds (1995-1999).

The Alcohol Needs Assessment Research Project (ANARP) in England found the prevalence of alcohol dependence to be 4% in 16- to 64-year-old adults: 6% of men and 2% of women. This equates to a population of 1.1 million people in England with alcohol dependence in 2000. This population increased to 1.6 million in 2007. In terms of productivity, alcohol contributes to absenteeism, accidents in the workplace and decline in work performance. Up to 17 million working days are lost annually in the UK due to alcohol-related absences and 58,000 working years are lost annually due to premature deaths related to alcohol.

VI.2.2 Summary of treatment benefits

Alcohol dependence:

Seventy male alcohol-dependent patients participated in a 12-week, double-blind, placebo-controlled trial of naltrexone hydrochloride (50 mg/d) as an adjunct to treatment following alcohol detoxification. Subjects taking naltrexone reported significantly less alcohol craving and days in which any alcohol was consumed. During the 12-week study, only 23% of the naltrexone-treated subjects met the criteria for a relapse, whereas 54.3% of the placebo-treated subjects relapsed. The primary effect of naltrexone was seen in patients who drank any alcohol while attending outpatient treatment. Nineteen (95%) of the 20 placebo-treated patients relapsed after they sampled alcohol, while only eight (50%) of 16 naltrexone-treated patients exposed to alcohol met relapse criteria. Naltrexone was not associated with mood changes or other psychiatric symptoms. Study results suggest that naltrexone may be effective adjunct to treatment in alcohol-dependent subjects, particularly in preventing alcohol relapse.

VI.2.3 Unknowns relating to treatment benefits

None

VI.2.4 Summary of safety concerns

None

VI.2.5 Summary of additional risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SmPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimizing them. An abbreviated version of this in lay language is provided in the form of the package leaflet (PL). The measures in these documents are known as routine risk minimisation measures.

This medicine has no additional risk minimization measures.

VI.2.6 Planned post authorisation development plan

Not applicable

VI.2.7 Summary of changes to the risk management plan over time

Version	Date	Safety Concern	Comment
2.0	27-Jun-2017	The important identified risks and missing information have been deleted from the safety specification as suggested by health authority.	RMP has been updated as per Preliminary Variation Assessment Report of Type II variation (FI/H/781/01/II/05) received from RMS (Finland).