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A.1 Acamprosate – 333 mg oral tablet

MSF strongly supports the inclusion of acamprosate, in Section 24.5 “Medicines for disorders due to psychoactive substance use” of the Core List of the WHO Model List of Essential Medicines (EML), for maintenance treatment of adults with alcohol use disorder.

Currently, the EML does not list any medication for the treatment of alcohol use disorder.

The 2018 WHO Global Status Report on Alcohol and Health states that in 2016, the harmful use of alcohol resulted in some 3 million deaths (5.3% of all deaths) worldwide. Overall, harmful use of alcohol is responsible for 5.1% of the global burden of disease. Mortality resulting from alcohol consumption is higher than that caused by diseases such as tuberculosis, HIV/AIDS and diabetes. Harmful use of alcohol is accountable for 7.1% and 2.2% of the global burden of disease for males and females respectively. Alcohol is the leading risk factor for premature mortality and disability among those aged 15 to 49 years, accounting for 10% of all deaths in this age group. Disadvantaged and especially vulnerable populations have higher rates of alcohol-related death and hospitalization. Importantly, the treatment coverage for alcohol dependence in 2016 was close to zero in low- or lower-middle-income countries, although the level of treatment coverage in most countries is not known¹. According to a recent meta-analysis, one in six people with alcohol use disorder receive treatment and rates are even lower in low and lower-middle-income countries².

The 2016 WHO mhGAP Intervention Guide for Mental, Neurological and Substance Use Disorders in Non-Specialized Health Settings recommends considering pharmacologic intervention to prevent relapse in alcohol dependence, including acamprosate, naltrexone and disulfiram. With these medications, an effective response may include a reduction in the quantity and frequency of alcohol consumption, if not complete abstinence. Acamprosate is more effective if initiated after detoxification is completed, but its pharmacokinetics are not altered by co-administration with alcohol or benzodiazepines and can therefore be safely used prior to alcohol cessation and during relapse. Acamprosate dosage is a thrice-daily intake of 666 mg for 12 months. In moderate kidney disease, the recommended thrice-daily intake is 333 mg. Adverse effects can be: diarrhoea, flatulence, nausea/vomiting, abdominal pain, depression, anxiety, suicidality, itching. Occasionally, a

¹ World Health Organization. Global Status Report on Alcohol and Health. 2018.

² Mekonen T, Chan GCK, Connor J, Hall W, Hides L, Leung J. Treatment rates for alcohol use disorders: a systematic review and meta-analysis. *Addiction*. 2021 Oct;116(10):2617-2634.

maculopapular rash can occur, and rarely, bullous skin reactions³. Acamprosate is contra-indicated in severe kidney or liver disease and should be avoided during pregnancy.

Several national guidelines include acamprosate (alongside naltrexone) as a recommended first-line medicine (as naltrexone) in the treatment for alcohol use disorder^{4 5}.

MSF would like to draw the attention of The Expert Committee on the following facts:

- An application for the inclusion of naltrexone (both oral and extended-release injectable formulations), another medication for the treatment of alcohol use disorder is also submitted to the 24th Expert Committee.
- Unlike naltrexone, acamprosate does not present the risk of hepatotoxicity, hence the need for liver function test monitoring which can be a particular challenge in low- and middle-income countries, in settings where monitoring of liver function is not feasible (due to limited access to laboratory testing and cost of testing).
- Acamprosate would be a very useful option for patients receiving opioid substitution treatment and who have comorbid alcohol use disorder, as they would be able to continue their opioid substitution treatment and also take acamprosate.
- According to the application, acamprosate is available in USA, Australia, India and UK, highly regulated countries and is off patent. The inclusion of acamprosate in the EML will serve as a basis for National Essential Medicines lists and therefore will attract additional manufacturers and generic producers in order to improve affordability and accessibility, particularly in low- and middle-income countries.

In light of these elements, MSF urges the 24th Expert Committee on the Selection and Use of Essential Medicines to include acamprosate in Section 24.5 “Medicines for disorders due to psychoactive substance use” of the Core List of the WHO Model List of Essential Medicines, for maintenance treatment of adults with alcohol use disorder.



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³ mhGAP Intervention Guide for Mental, Neurological and Substance Use Disorders in Non-Specialized Health Settings: Mental Health Gap Action Programme (mhGAP): Version 2.0. Geneva: World Health Organization; 2016.

⁴ American Psychiatric Association. American Psychiatric Association Practice Guideline for the Pharmacological Treatment of Patients With Alcohol Use Disorder. January 2018

⁵ National Collaborating Centre for Mental Health (UK). Alcohol-Use Disorders: Diagnosis, Assessment and Management of Harmful Drinking and Alcohol Dependence. British Psychological Society; 2011. (NICE Clinical Guidelines, No. 115.)