

CMHP 23 Southway Burgess Hill West Sussex RH15 9SY

Email: info@cmhp.org.uk

15th April 2024

The Rt Hon Victoria Atkins MP Secretary of State Department of Health and Social Care 39 Victoria Street London SW1H OEU

Dear Secretary of State,

Risks of Proposed Withdrawal of Intramuscular Pabrinex®

We are writing to express our concern at the proposed discontinuation of the intramuscular (IM) preparation of Pabrinex® which was communicated via a recent Department of Health Medicines Supply Notification [MSN/2024/038]. This will have a significant impact on the safe and effective treatment of people who are dependent on alcohol. Alcohol dependent people must receive the interventions they require in a timely way since alcohol is a leading cause of death in the UK and concerns about problematic use and its associated complications have only increased since the pandemic¹.

Wernicke-Korsakoff Syndrome (WKS) is a serious complication of thiamine (vitamin B1) deficiency, which if inappropriately managed, can result in lasting brain injury and fatality. It is associated with the dependent use of alcohol and is perhaps of greatest concern during alcohol detoxification. Vitamin B supplementation therefore plays a critical role in protecting against (and treating) WKS. For individuals known to be at greater risk of experiencing WKS, oral thiamine is not clinically effective, as absorption from this route is saturated at 5-10mg per dose in healthy individuals and reduced to negligible amounts in people who are alcohol dependent²⁻⁴. Additionally, thiamine stores need to be replaced as quickly as possible and high circulating levels are required for passive diffusion into the central nervous system. Consequently, there is a requirement for an injectable formulation in this situation.

Pabrinex® is currently the only licensed form of injectable B vitamins available in the UK. Hence treatment providers are now tasked with sourcing alternative unlicensed products. This has the potential to create medico-legal challenges, contribute to delays in interventions being provided, and will increase workloads and financial pressures in an already over-stretched system.



Furthermore, the majority of mental health, secure environments, specialist detoxification and community alcohol treatment service settings across the UK rely solely on the IM preparation for the following reasons:

- IM administration of Pabrinex® is associated with a lower risk of anaphylaxis as opposed to an intravenous (IV) infusion^{4,5}. The IM route is therefore favoured, especially by settings that are geographically distant and distinct from secondary care medical facilities which are required in medical emergencies.
- Individuals may concomitantly use drugs IV and/or have poor cardiovascular health which can create difficulties when inserting IV cannulas. Additionally, whilst cannulas remain in situ, this can create additional risks for example, if they are misused for the IV administration of other substances.
- Healthcare professionals working in these environments may not have the training or opportunity to maintain IV administration competencies.

Sourcing inpatient provision to facilitate IV administration is significantly more expensive and can be extremely difficult, especially in the current climate. This may necessitate individuals utilising alternative and already saturated services such as accident and emergency/urgent care or out-of-hours providers. These alternative settings may not be desired by or be practicable for people who are dependent on alcohol, creating further barriers to an already vulnerable population receiving timely interventions and will worsen health inequalities.

Additionally, it is unclear what impact and delay this may have on the publication of the eagerly awaited UK clinical guidelines for alcohol treatment, which our members reviewed and contributed to during the consultation.

We hope the above points are considered in their entirety by the convened clinical reference group, with special consideration to services that rely on the IM preparation alone.

Yours sincerely,

Karen Shuker

College of Mental Health Pharmacy President

Registered address:

CMHP, 23 Southway, Burgess Hill, West Sussex RH15 9SY Company Registration No. 7124743 - Registered Charity No. 1141467



References

- Office for Health Improvement and Disparities. Public health Profiles 2024 https://fingertips.phe.org.uk © Crown copyright 2024. Accessed: 15.04.2024
- 2. Tallaksen C, Sande A, Bøhmer T, Bell H and Karlsen J. <u>Kinetics of thiamin and thiamin phosphate esters in human blood, plasma and urine after 50 mg intravenously or orally</u>. European Journal of Clinical Pharmacology 1993: volume 44, pages73–78
- 3. Weber W and Kewitz H. <u>Determination of thiamine in human plasma</u> and its pharmacokinetics. European Journal of Clinical Pharmacology 1985: volume 28, issue 2, pages 213-219
- 4. Thomson A and Marshall EJ. <u>The treatment of patients at risk of developing Wernicke's encephalopathy in the community</u>. Alcohol and Alcoholism 2006: volume 41, issue 2, pages 159-167
- 5. Cook C, Hallwood P and Thomson A. <u>B vitamin deficiency and neuropsychiatric syndromes in alcohol misuse</u>. Alcohol and Alcoholism 1998: volume 33, issue 4, pages 317–336