Vitamin B Complex Decision Document

Drug	Vitamin B Co preparations
Indication	Refeeding syndrome; Vitamin B deficiency states; peripheral neuropathy; prevention of Wernicke's Encephalopathy
Decision	NHS West Essex Clinical Commissioning Group does not commission Vitamin B Compound tablets - DOUBLE RED status (not for primary or secondary care prescribing). NHS West Essex Clinical Commissioning Group commissions Vitamin B Compound strong tablets only for the following patients: • Refeeding syndrome - 10 days treatment - RED status (use in secondary care only, not recommended for primary care prescribing). • Treatment of identified vitamin B deficiency states - RED status (specialist use only, not recommended for primary care prescribing). • For all other indications (including prevention of Wernicke's encephalopathy, and peripheral neuropathy): vitamin B compound strong is not recommended for use - DOUBLE RED status.
Date	29 th August 2019
Evidence	NICE CG32 Nutrition support for adults: oral nutritional support, enteral tube feeding and parenteral nutrition (Published February 2006; Last updated August 2017) The prescription for people at high risk of developing refeeding problems should consider: • providing immediately before and during the first 10 days of feeding: oral thiamine 200–300 mg daily, vitamin B co strong 1 or 2 tablets, three times a day (or full dose daily intravenous vitamin B preparation, if necessary) and a balanced multivitamin/trace element supplement once daily Wernicke's encephalopathy NICE CG100 Alcohol-use disorders: diagnosis and management of physical complications (Published June 2010; Last updated April 2017) 1.2.1.1 Offer thiamine to people at high risk of developing, or with suspected, Wernicke's encephalopathy. Thiamine should be given in doses toward the upper end of the 'British national formulary' range. It should be given orally or parenterally as described in recommendations 1.2.1.2 to 1.2.1.4. [2010] 1.2.1.2 Offer prophylactic oral thiamine to harmful or dependent drinkers: • if they are malnourished or at risk of malnourishment or • if they are in acute withdrawal or • before and during a planned medically assisted alcohol withdrawal. [2010] 1.2.1.3 Offer prophylactic parenteral thiamine followed by oral thiamine to harmful or dependent drinkers: • if they are malnourished or at risk of malnourishment or • if they are malnourished or at risk of malnourishment or • if they are malnourished or at risk of malnourishment or

encephalopathy, particularly if the person is intoxicated. Parenteral treatment should be given for a minimum of 5 days, unless Wernicke's encephalopathy is excluded. Oral thiamine treatment should follow parenteral therapy. [2010]

Peripheral Neuropathy

Ang et al (2008) Vitamin B for treating peripheral neuropathy. Cochrane Database of Systematic Reviews

Cochrane review Vitamin B for treating peripheral neuropathy (2008) advises there is insufficient evidence to determine whether vitamin B is beneficial or harmful in this condition.

Position Statement:

NHS West Essex Clinical Commissioning Group **does not** commission Vitamin B Compound - DOUBLE RED status (not for primary or secondary care prescribing).

NHS West Essex Clinical Commissioning Group commissions Vitamin B Compound strong only for the following patients:

- Refeeding syndrome 10 days treatment RED status (use in secondary care only, not recommended for primary care prescribing).
- Treatment of identified vitamin B deficiency states RED status (use in secondary care only, not recommended for primary care prescribing).
- For all other indications (including alcohol abuse, peripheral neuropathy): vitamin B compound strong is not recommended for use – DOUBLE RED status.

Rationale for recommendation

Effectiveness

Vitamins were included in the NHS England - <u>Conditions for which over the counter items should not routinely be prescribed in primary care: Guidance for CCGs</u> (29 March 2018)

Vitamins and minerals should not be routinely prescribed in primary care due to limited evidence of clinical effectiveness.

Exceptions:

- Medically diagnosed deficiency, including for those patients who may have a lifelong or chronic condition or have undergone surgery that results in malabsorption. Continuing need should however be reviewed on a regular basis. NB maintenance or preventative treatment is not an exception.
- · Calcium and vitamin D for osteoporosis.
- Malnutrition including alcoholism (see NICE guidance)
- Patients suitable to receive Healthy start vitamins for pregnancy or children between the ages 6 months to their fourth birthday. (NB this is not on prescription but commissioned separately)

Medication for the treatment of Alcohol Use Disorder: A Brief Guide¹

Testing for vitamin deficiencies:

Individuals with alcohol use disorder may not consume a healthful diet, resulting in vitamin deficiencies that lead to abnormal cellular function. For example, deficiencies in thiamine, folic acid, and pyridoxine are seen in people with physiological alcohol dependence, and those deficiencies contribute to abnormal cell function. Vitamin deficiencies may also lead to Wernicke-Korsakoff/amnesic syndrome in patients whose alcohol consumption is very excessive.

<u>PrescQIPP Bulletin 107: The prescribing of Vitamins and Minerals, including vitamin B preparations</u> (DROP-List)

Deficiency of the B vitamins, with the exception of vitamin B12, is rare in the UK and is usually treated by preparations containing thiamine (B1), riboflavin (B2), and nicotinamide. Pabrinex® I/V and I/M high potency injections, vitamin B compound tablets, vitamin B compound strong tablets and Vigranon B® all contain thiamine, riboflavin, and nicotinamide.

Vitamin B compound tablets, vitamin B compound strong tablets and Vigranon B® have the symbol which denotes that are considered by the Joint Formulary Committee to be less suitable for prescribing. Consequently they should not be considered as drugs of first choice, but may be justifiable in certain circumstances.

However Vigranon B® syrup is listed in Part XVIIIA of the Drug Tariff - Drugs, Medicines and Other Substances not to be ordered under a General Medical Services Contract so it is not permitted on FP10 and will not be reimbursed by the NHS Prescription Services.

Oral thiamine is recommended by both NICE and the Scottish Intercollegiate Guidelines Network (SIGN) for patients who have a chronic alcohol problem and whose diet may be deficient. NICE recommends prescribing prophylactic oral thiamine for harmful or dependent drinkers if they are malnourished, at risk of malnourishment, they have decompensated liver disease, are in acute withdrawal or before and during a planned medically assisted alcohol withdrawal. The guidelines recommend prescribing thiamine in doses toward the upper end of the BNF dosage (for mild deficiency 25–100 mg daily and for severe deficiency, 200–300 mg daily in divided doses). They do not recommend the prescribing of vitamin B complex preparations.

Safety

Excess vitamin B is readily excreted, therefore no serious problems are anticipated for the administration of vitamin B compound strong.²

Patient factors

Neither vitamin B compound NOR vitamin B compound strong tablets contains enough thiamine for treatment/prophylaxis of Wernicke's encephalopathy.

- Prescribe prophylactic oral thiamine 200 to 300 mg daily in divided doses to harmful or dependent drinkers for prevention of WE continued for as long as malnutrition is present and/or during periods of continued alcohol consumption. ⁴
- Review patients prescribed thiamine with a view to stopping if the patient has been abstinent for 6 weeks or more and has regained adequate nutritional status. 4
- Patients who require continued treatment with thiamine should be reviewed at appropriate intervals depending on individual circumstances.⁴

The B vitamin content of OTC vitamin B or OTC multivitamin & mineral products is almost identical to the B vitamin content of prescribed vitamin B compound (see table below).

References

- 1. National Institute on Alcohol Abuse and Alcoholism Medication for the treatment of Alcohol Use Disorder: A Brief Guide (2015)
- 2. SmPC Vitamin B Compound Strong Electronic Medicines Compendium
- 3. British National Formulary https://bnf.nice.org.uk/treatment-summary/alcohol-dependence.html [Accessed 11.1.19]
- 4. Regional Medicines Optimisation Committee (RMOC) Position Statement <u>Oral vitamin B</u> supplementation in alcoholism November 2019

Acknowledgements

 Hertfordshire Medicines Management Committee Guidance on the use of Use of vitamin B compound and compound strong (June 2019 HMMC Meeting)

Vitamin B content of the following:

	Government dietary recommendations ¹	Vitamin B co strong ²	Vigranon-B Syrup ¹	Forceval Capsules ¹	Vitamin B compound ³	Valupak Multivitamin ⁴	Boots A-Z Complete Vitamins and Minerals ⁵	Tesco A-Z Multivitamins and minerals ⁶
Nicotinamide/Niacin	16.5mg/day (men) 13.2mg/day (women)	20mg	20mg		15mg	16mg	16mg	16mg
Pyridoxine (B6)	1.4mg/ day (men) 1.2mg/day (women)	2mg	2mg	2mg		1.4mg	1.4mg	1.4mg
Riboflavin (B2)	1.3mg/day (men) 1.1mg/day (women)	2mg	2.74mg	1.6mg	1mg	1.4mg	1.4mg	1.4mg
Thiamine (B1)	1mg/day (men) 0.8mg/day (women)	4.85mg	5mg	1.2mg	1mg	1.1mg	1.1mg	1.1mg
Vitamin B12 (Cyanocobalamin)	1.5mcg/day			3.0mcg		2.5mcg	2.5mcg	2.5mcg
Dexapanthenol/Pantothenic acid (Vitamin B5)			3mg			6mg	6mg	6mg
Folic Acid/Folate	200mcg/day					200mcg	200mcg	200mcg

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¹ Government dietary recommendations [Accessed 15.7.19]

² SmPC <u>https://www.medicines.org.uk/emc</u> [Accessed 15.7.19]

³ BNF https://bnf.nice.org.uk/medicinal-forms/vitamin-b-complex.html

⁴ http://www.valupak.co.uk/documents/content/63/VP361.pdf

⁵ Boots A-Z Complete Vitamins and Minerals [Accessed 15.7.19]

⁶ Tesco A-Z Multiviatmins and minerals [Accessed 15.7.19]

Document History	Consultation Process	Amendments
Produced by West Essex Medicines Management Team	MOPB August 2019	
Updated in line with Regional Medicines Optimisation Committee (RMOC) Position Statement Oral vitamin B supplementation in alcoholism November 2019	MOPB January 2020	 Treatment of identified vitamin B deficiency states – specialist use only. Previously secondary care only. Prescribe prophylactic oral thiamine 200 to 300 mg daily in divided doses to harmful or dependent drinkers for prevention of WE continued for as long as malnutrition is present and/or during periods of continued alcohol consumption. Review patients prescribed thiamine with a view to stopping if the patient has been abstinent for 6 weeks or more and has regained adequate nutritional status. Patients who require continued treatment with thiamine should be reviewed at appropriate intervals depending on individual circumstances.