Oral vitamin B supplementation in alcoholism

[Prescribing Oversight Committee ClinDoc 058]

For the latest information on interactions and adverse effects, always consult the latest version of the Summary of Product Characteristics (SPC), which can be found at: http://www.medicines.org.uk/

Approval and Authorisation

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<tr>
<th>Approved by</th>
<th>Job Title</th>
<th>Date</th>
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<tr>
<td>Prescribing Oversight Committee</td>
<td>POC Chair</td>
<td>22/07/2020</td>
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Change History

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<td>22/07/2020</td>
<td>D.Pollock</td>
<td>New document, adapted from the RMOC Position Statement on oral vitamin B (Nov 2019)</td>
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This prescribing guideline remains open to review considering any new evidence

This guideline should only be viewed online and will no longer be valid if printed off or saved locally
Position Statement Summary

• Do not initiate vitamin B compound or vitamin B compound strong tablets for any of the following indications:
  - Prevention of Wernicke’s Encephalopathy (WE) in alcoholism
  - Dietary supplementation
  - Prevention of deficiency
  - Maintenance treatment following treatment of deficiency

• Review all existing patients prescribed vitamin B complex preparations with a view to stopping treatment in all but exceptional circumstances, such as in those patients with a medically diagnosed deficiency due to lifelong or chronic condition, or following surgery that results in malabsorption. If all relevant patient factors have been taken into account and it is considered appropriate to stop, treatment may be stopped immediately.

• The decision to discontinue treatment should be carefully explained to the patient, and should emphasise the positive aspects of discontinued prescribing of drugs with a low clinical value.

• Advise patients who wish to use these vitamin B preparations as dietary supplements to purchase them over the counter.

• 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.
Introduction

The Regional Medicines Optimisation Committee reviewed the use of vitamin B supplementation in alcoholism, taking into account relevant guidance published by NICE and NHS England as well as information from other specialist sources. The advice of the RMOC is summarised as follows:

Vitamin B complex preparations

- Due to a lack of evidence on their efficacy and safety, vitamin B complex preparations (vitamin B compound and vitamin B compound strong tablets) should not be prescribed for prevention of Wernicke’s Encephalopathy (WE) in alcoholism.
- Vitamin B complex preparations should not be prescribed for preventing deficiency or for maintenance treatment following treatment for deficiency.
- Vitamin B complex preparations should not be prescribed as dietary supplements. Patients who wish to use them for dietary supplementation should be advised to purchase them over the counter.
- Vitamin B compound strong tablets may be prescribed on a short-term basis (10 days) for patients at risk of refeeding syndrome. This also applies to patients who are not harmful or dependent drinkers.
- In rare cases where there might be a justifiable reason for prescribing vitamin B complex e.g. medically diagnosed deficiency or chronic malabsorption, vitamin B compound strong and not vitamin B compound should be prescribed as it represents better value for money.

Thiamine

- In line with NICE guidance, oral thiamine should be prescribed for the prevention of WE to harmful or dependent drinkers in whom any of the following apply:
  - They are malnourished or at risk of malnourishment
  - They have decompensated liver disease
  - They are in acute withdrawal
  - Before and during a planned medically assisted alcohol withdrawal
- The recommended dose is 200 to 300 mg daily in divided doses.
- Thiamine should be continued for as long as malnutrition is present and/or during periods of continued alcohol consumption.
- Following successful alcohol withdrawal, thiamine should be continued for 6 weeks. If after this time the patient remains abstinent and has regained adequate nutritional status, thiamine should be discontinued. Thiamine should be restarted if the patient starts drinking again.
- Continuing need for thiamine should be reviewed at appropriate intervals which may depend on individual patient circumstances.

Vitamin B supplementation in harmful or dependent drinkers

Wernicke’s encephalopathy (WE) is an acute neurological state comprising of mental confusion, ataxia and ophthalmoplegia which may develop in harmful or dependent drinkers due to thiamine deficiency. (1,2) Thiamine deficiency is common in these patients due to factors such as poor diet, poor absorption of nutrients and a high

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<tr>
<th>Author</th>
<th>D. Pollock</th>
<th>Date of production:</th>
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<td>Job Title</td>
<td>Lead Interface Pharmacist</td>
<td>Review Date:</td>
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<td>Protocol Lead</td>
<td>D. Pollock</td>
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demand for the vitamin (a coenzyme in alcohol metabolism). (3)

Historically, vitamin B complex preparations (vitamin B compound and vitamin B compound strong tablets) have been used in addition to thiamine as prophylaxis of WE. These preparations contain combinations of various B vitamins – see table below. (4)

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<tr>
<th></th>
<th>Nicotinamide</th>
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<tr>
<td>Vitamin B compound</td>
<td>15 mg</td>
<td>-</td>
<td>1mg</td>
<td>1mg</td>
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**NICE CG100** recommends that prophylactic oral thiamine prescribed at the upper end of the BNF range should be offered to harmful or dependent drinkers if any of the following apply: (5)

- They are malnourished or at risk of malnourishment
- They have decompensated liver disease
- They are in acute withdrawal
- Before and during a planned medically-assisted alcohol withdrawal

The upper end of the dose range for thiamine in the BNF is 200 to 300 mg daily in divided doses. [4c]

The guideline makes no reference to the use of oral vitamin B complex preparations for this indication. This is likely due to the lack of published evidence to support the use of vitamin B complex preparations in harmful or dependent drinkers.

Due to an absence of data, there is a lack of clear guidance on the duration of treatment with thiamine in harmful or dependent drinkers. One expert source recommends that oral thiamine should be continued for as long as needed i.e. where diet is inadequate or alcohol consumption is resumed. (6) The NICE CG100 full guideline notes that once alcohol is stopped, oral thiamine absorption may take six weeks to return to normal. (7) On this basis, it would seem reasonable to continue thiamine for 6 weeks after alcohol withdrawal.

**Vitamin B supplementation in other indications**

**Refeeding syndrome**

NICE CG32 recommends that for people at high risk of developing refeeding problems, the following should be provided 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. (8)

**Dietary supplementation**
Evidence on the clinical benefit of vitamin B complex preparations used as dietary supplements is lacking. Vitamins are included in NHS England guidance on conditions for which over the counter items should not routinely be prescribed in primary care. Due to insufficient evidence of their clinical effectiveness they should not routinely be prescribed in primary care unless specified exceptions are met. (9) Vitamin B complex preparations are widely available to purchase over the counter if patients wish to use them to use as dietary supplements.

**Deficiency**

Vitamin B compound and vitamin B compound strong tablets are licensed for the prophylaxis and treatment of deficiency respectively. (4) However, deficiency of the B vitamins, other than vitamin B12 and thiamine in harmful or dependent drinkers, is rare in the UK. (3,4) The BNF regards these products as less suitable for prescribing possibly due to their questionable clinical benefit - they should not be considered as drugs of first choice, but may be justifiable in certain circumstances. (10) The exceptions in the NHS England guidance that allow vitamins to be prescribed include medically diagnosed deficiency, including for those patients who may have a lifelong or chronic condition or have undergone surgery that results in malabsorption; and malnutrition including alcoholism. Maintenance or preventative treatment is not considered an exception. (9)

If the prescribing of vitamin B complex is considered justifiable based on the circumstances described above, vitamin B compound strong tablets should be prescribed as they represent better value for money compared to vitamin B compound tablets (28 x vitamin B compound tablets = £26.63 vs 28 x vitamin B compound strong tablets = £1.97). (11)
References