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PrescQIPP Community Interest Company

Vitamins and minerals

This bulletin focuses on the prescribing of vitamin preparations, vitamin and mineral preparations, and their review. The aim is to discontinue those that are being prescribed as dietary supplements or as a general "pick-me-up" as these may be unnecessary or may be purchased over-the-counter. This bulletin may therefore be used to support a review of these preparations as a medicines optimisation project.

National prescribing guidance advises that vitamins and minerals should not be prescribed as dietary supplements or as a general "pick-me-up",[1] and that these preparations should not be routinely prescribed in primary care due to limited evidence of clinical effectiveness.[2]

This bulletin does not cover the prescribing of: vitamin K; vitamin D;[3] omega−3 fatty acids;[4] calcium and vitamin D preparations for osteoporosis; or the prescribing of vitamin and mineral supplements recommended by the Advisory Committee on Borderline Substances (ACBS) as borderline substances in patients with malnutrition.[5]

Recommendations

- Review all patients prescribed vitamin preparations, and vitamin and mineral preparations to ensure that prescribing is only for the management of actual or potential vitamin or mineral deficiency.
- Discontinue prescribing for preparations that are being prescribed as dietary supplements or as a general "pick-me-up".
- Recommend eating a healthy, varied, and well-balanced diet to provide the vitamins and minerals needed and consider using this medicines optimisation project as an opportunity to promote healthy eating to all patients.
- If patients still want to take vitamins and minerals for dietary supplementation or as a "pick-me-up" they should be advised to purchase them over-the-counter and seek advice on appropriate products from the community pharmacist.
- Do not initiate new prescriptions for these preparations unless they are for the management of actual or potential vitamin and mineral deficiency.
- Some patients may be eligible for NHS Healthy Start vitamins which are specifically designed for use during pregnancy, whilst breast feeding and for growing children from birth up to the age of four years. In Scotland, Healthy Start vitamins are offered to all pregnant women, and a vitamin D supplement is currently offered to all breastfeeding women and children under 12 months.
- Review all patients prescribed vitamin B preparations to ensure that they are appropriate, and that the most cost-effective preparation is prescribed. For example, prophylactic oral thiamine at a dose of 200 to 300 mg daily in divided doses in alcohol dependency.

National guidance

NHS England guidance on items that should not routinely be prescribed in primary care

In 2018, NHS England published guidance on items that should not routinely be prescribed in primary care. CCGs are advised that vitamins and minerals should not be routinely prescribed in primary care due to limited evidence of clinical effectiveness.[2]

This guidance states that:

- Vitamins and minerals are essential nutrients which most people can and should get from eating a healthy, varied, and balanced diet. In most cases, dietary supplementation is unnecessary.
- Many vitamin and mineral supplements are classified as foods and not medicines; they therefore have not gone through the strict criteria laid down by the Medicines and Health Regulatory Authority (MHRA) to confirm their quality, safety and efficacy before reaching the market.
- Any prescribing not in line with listed exceptions in the guidance. The exceptions are:
  - 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.
  - Patients suitable to receive Healthy Start Vitamins for pregnancy or children between the ages of six months to their fourth birthday. (NB. this is not on prescription but commissioned separately.)

All Wales Medicines Strategy Group guidance on items that should not routinely be prescribed in primary care

Similar guidance has been published in Wales which states that there is insufficient high-quality evidence to demonstrate the clinical effectiveness of vitamins and minerals. This guidance highlights the prescribing of ascorbic acid, selenium, and Ketovite as preparations for review.[6]

To support this medicines optimisation workstream, PrescQIPP has published a number of resources.[7-9]

A healthy, varied, and balanced diet

Vitamins and minerals are essential nutrients which most people should get from eating a healthy, varied, and balanced diet.[10,11] Eating a healthy, balanced diet is an important part of maintaining good health. A healthy diet means eating a wide variety of foods in the right proportions and consuming the right amount of food and drink to achieve and maintain a healthy body weight.[12] The Eatwell Guide[13,14] is a very useful tool and shows that to have a healthy, balanced diet, people should try to choose a variety of different foods from the five main food groups to get a wide range of nutrients and:

- Eat at least five portions of a variety of fruit and vegetables every day.
- Base meals on higher fibre starchy foods like potatoes, brown bread, brown rice or wholewheat pasta (higher fibre starchy food should make up just over a third of the food a person eats).
- Have some dairy or dairy alternatives (such as soya drinks).
- Eat some beans, pulses, fish, eggs, meat and other protein.
- Choose unsaturated oils and spreads, and eat them in small amounts.
- Drink plenty of fluids (at least six to eight cups or glasses a day).

Foods and drinks that are high in fat, salt and sugar, should be consumed less often and in small amounts. Most people in the UK eat and drink too many calories, too much saturated fat, sugar and salt, and not enough fruit, vegetables, oily fish or fibre.[13]

There are numerous online resources available which patients can be signposted to that offer lifestyle advice covering healthy eating to achieve a nutritious diet and a healthy weight.

These include:

- NHS Choices www.nhs.uk/live-well/eat-well/
- The Eatwell Guide Booklet www.gov.uk/government/publications/the-eatwell-guide
- The British Nutrition Foundation healthy diet recommendations https://www.nutrition.org.uk/healthy-sustainable-diets/healthy-and-sustainable-diets/a-healthy-balanced-diet/
- The Association of UK Dietician food fact sheets www.bda.uk.com/foodfacts/home
- Public Health England (PHE) eating well campaigns https://campaignresources.phe.gov.uk/resources/campaigns
- Better Health https://www.nhs.uk/better-health/ is the ongoing PHE campaign for adults, and Change4Life www.nhs.uk/change4life is the ongoing PHE campaign for children.

As part of this medicines optimisation project consider utilising these resources in order to promote healthy eating to all patients. In England, all community pharmacies are now contractually required to be Healthy Living Pharmacies as part of their essential services,[15] and in Scotland the Public Health Service is one of the four core community pharmacy services.[16] This enables community pharmacy to support patients with wider public health messages and interventions.

Know your vitamins

As part of this medicines optimisation project, take the opportunity to review your knowledge of vitamins including:

- Their functions in the body.
- How common a deficiency is likely to be and the clinical implications of a deficiency.
- Good food sources for vitamin groups.
- The daily recommended amounts (In 2016, PHE published a report on dietary recommendations for both children and adults).[17]
- Clinical evidence for the use of vitamins. For example, there is evidence to suggest that vitamin B6 (pyridoxine hydrochloride) may provide some benefit in premenstrual syndrome. However, claims that vitamin C (ascorbic acid) ameliorates colds or promotes wound healing have not been proven. In addition, vitamin E (tocopherol) has been tried for various conditions but there is little scientific evidence of its value.[1,18]
- Any potential harm from taking too much, particularly for vitamin A, vitamin B6 and vitamin C. Research suggests that taking more than 1.5 mg a day of vitamin A over many years may affect the bones, making them more likely to fracture. This is particularly important for older people, especially women, who are already at increased risk of osteoporosis. If a person eats liver every week, they should not take supplements that contain vitamin A. High levels of vitamin A may cause birth defects, therefore women who are (or may become) pregnant are advised not to take vitamin A supplements (including fish liver oil supplements); nor should they eat liver or products such as liver paté or liver sausage. For vitamin B6, taking 200mg or more a day can lead to peripheral neuropathy (a loss of feeling in the arms and legs). And for vitamin C, taking more than 1,000mg per day can cause gastrointestinal side effects of stomach pain, diarrhoea and flatulence.[10]

Information from NHS Choices[10] and the BNF[1] provides information on each of the main vitamin groups.

Vitamins and minerals for mothers and young children

Ensuring that a woman is well-nourished, both before and during pregnancy, is crucial for the health of the woman and that of the unborn child. Many nutritional supplements are heavily marketed to women for all stages of pregnancy. However, much of the evidence for vitamin supplementation in pregnancy comes from studies carried out in low-income countries where women are more likely to be undernourished or malnourished than within the UK population.[19]

Folic acid and vitamin D supplements are particularly recommended in pregnancy to reduce the risk of birth defects and to keep bones, teeth and muscles healthy, respectively.[20]

Vitamins A, C and D supplements are recommended for all children aged six months to five years.[21] This is as a precaution because growing children may not get enough, especially those not eating a varied diet, such as fussy eaters.[22]

Healthy Start vitamins in England and Wales

Some patients on lower incomes will be eligible for the NHS Healthy Start Scheme so do not need to be prescribed vitamins and minerals.[23] These preparations are available free of charge from local distribution points. Local Authority public health teams can be contacted to find out where these distribution points are located. Healthcare professionals play a key role in signposting the availability of the free Healthy Start vitamins and a toolkit for organisations is available at https://media.nhsbsa.nhs.uk/resources/f/voucher-value-increase-2021/toolkit. The Healthy Start website states that research shows that women who are introduced to the Scheme by a health professional, who takes time to explain its public health context and health benefits, are more likely to understand the benefits rather than as a simple financial contribution. They may therefore be more likely to make best use of the Scheme.

Pregnant women, women with a child under 12 months and children aged up to four years are entitled to free Healthy Start vitamins. Healthy Start vitamins contain:

- Vitamins A, C and D for children aged from birth to four years (children who are having 500ml or more of formula a day do not need Healthy Start vitamins).
- Folic acid and vitamins C and D for pregnant and breastfeeding women.

The Healthy Start website states that Healthy Start vitamins are important because:

- 8% of children under five in the UK don't have enough vitamin A in their diet.
- Families in lower-income groups tend to have less vitamin C in their diet.
- All pregnant and breastfeeding women and young children are at risk of vitamin D deficiency.

Healthy Start vitamins in Scotland

In Scotland, Healthy Start vitamins are offered to all pregnant women. A vitamin D supplement is offered to all breastfeeding women, and children under 12 months (with a commitment to increase this offer to all children under 3 years of age).[24,25]

Examples of ACBS approved preparations in England and Wales

Although outside the scope of this bulletin, certain patients with malnutrition may require vitamin and mineral supplementation due to a clinical condition e.g. resulting from malnutrition. More information can be found in the National Institute for Health and Care Excellence (NICE) clinical guideline on nutrition support in adults[26] and in the PrescQIPP nutrition webkit at https://www.prescqipp.info/our-resources/webkits/nutrition/.

Prescribing of vitamin and mineral supplements recommended by the ACBS as borderline substances in patients with malnutrition or restrictive diets includes preparations such as:[5]

- DEKAs® preparations for the dietary management of patients with cystic fibrosis on the recommendation of a specialist in cystic fibrosis.
- Fruitivits® for the vitamin, mineral, and trace element supplementation required in children on restrictive therapeutic diets.
- Renavit® for dietary management of water-soluble vitamin deficiency in adults with renal failure on dialysis.

Examples of vitamin and mineral preparations that cannot be prescribed on NHS prescription in England, Wales and Scotland

Part XVIIIA of the Drug Tariff for England and Wales lists drugs, medicines and other substances not to be ordered under a General Medical Services Contract. It reproduces Schedule 1 to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004.[5] This list contains a number of vitamin and mineral preparations that cannot be prescribed including:

- Sanatogen® Multivitamins Tablets
- Pharmaton® Capsules
- Seven Seas® Multivitamin and Mineral Capsules
- Vigranon B® Complex Tablets, and Vigranon B® Syrup
- Vitamin B12 tablets (must be prescribed as cyanocobalamin).

This list is also reproduced in the Scottish Drug Tariff.[27]

Examples of vitamin and mineral preparations which can be prescribed on NHS prescription

The BNF and BNF for Children list vitamin and mineral preparations which can be prescribed.[1,28] These include:

- Forceval® capsules (for vitamin and mineral deficiency and as adjunct in synthetic diets) and Ketovite® tablets and liquid (for prevention of vitamin deficiency in disorders of carbohydrate or amino-acid metabolism, as an adjunct in restricted, specialised, or synthetic diets).
- Abidec® and Dalivit® drops for prevention of vitamin deficiency in children. Some children may be at risk of developing deficiencies because of an inadequate intake, impaired vitamin synthesis or malabsorption in disease states such as cystic fibrosis and Crohn's disease.[28] The BNF for Children advises that supplementation is not required if nutrient enriched feeds are used; consult a dietician for further advice.[29]

Vitamin B deficiency

Deficiency of the B vitamins, other than vitamin B12 or vitamin B1 (thiamine) deficiency in patients with alcohol dependence, is rare in the UK.[1]

Vitamin B12

Non-dietary vitamin B12 deficiency

Non-diet related vitamin B12 deficiency is an exception listed in the NHSE guidance on over the counter items that should not routinely be prescribed in primary care.[2] Hydroxocobalamin 1mg administered intramuscularly (IM) is the preferred method of treatment for non-diet-related vitamin B12 deficiency (e.g. pernicious anaemia) as it is retained in the body longer than cyanocobalamin. Where administration of IM hydroxocobalamin is not possible (e.g. during a pandemic) or not tolerated, oral 1mg cyanocobalamin may be considered as an alternative, provided sufficient doses are taken and there is good compliance with treatment.[30]

A licensed cyanocobalamin 1mg tablet (Orobalin®) is now available for haematological, neurological and other symptoms secondary to vitamin B12 deficiency, such as malabsorption of vitamin B12, due to the absence of intrinsic factor (pernicious anaemia), stomach resection or disease of the small intestine. The treatment dose is 2mg twice daily (usually for about eight weeks in pernicious anaemia). Thereafter, the maintenance / prophylactic dose is 1mg daily (lifelong prophylaxis is required in pernicious anaemia). If neuropathy is suspected, parenteral treatment should be used. Therefore, patients prescribed high-dose oral cyanocobalamin should be advised to contact their GP if they experience neurological or neuropsychiatric symptoms, such as pins and needles, numbness, problems with memory or concentration, or irritability.[31-33]

A cost comparison of providing vitamin B12 treatment and maintenance doses is provided in table 1. Hydroxocobalamin injections are the least costly option (excluding professional fees for administration), but where IM administration is not possible, then cyanocobalamin 1mg tablets (Orobalin®) are an alternative. Patients on multiple doses of cyanocobalamin 50 micrograms tablets to make up a 1mg dose may benefit from changing to a cyanocobalamin 1mg tablet to reduce the total number of tablets taken.

Table 1. Vitamin B12 cost comparisons[1,5,27]

Preparation	Maintenance dose	England and Wales - 28 day cost (£)	Scotland - 28 day cost (£)
Hydroxocobalamin 1mg IM injection (professional fees are an additional cost)	1mg monthly	£1.03	£1.77
Cyanocobalamin (Orobalin®) 1mg tablets	1mg daily	£9.33	£9.33
Cyanocobalamin 50 microgram tablets	50 – 150 micrograms daily	£8.70 - £26.08	£8.70 - £26.08

Diet related vitamin B12 deficiency

For diet related vitamin B12 deficiency, much lower doses of oral cyanocobalamin (50-150 micrograms daily) are required. These preparations are available as Pharmacy only (P) medicines which can be sold in a pharmacy or as food supplements from supermarkets or health food stores.[30] Patients should be advised to self-care with vitamin B12 (cyanocobalamin) (50 to 150 micrograms daily) and purchase these from a community pharmacy, supermarket or health food store.[2]

Wernicke's encephalopathy

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. Thiamine deficiency is common in these patients due to factors such as poor diet and poor absorption of nutrients.[34]

Thiamine should be offered to people at high risk of developing, or with suspected, WE. It should be given orally or parenterally as described in NICE clinical guidance Alcohol-use disorders: diagnosis and management of physical complications, which states:[35]

Offer prophylactic oral thiamine to harmful or dependent drinkers:

- if they are malnourished or at risk of malnourishment or
- if they have decompensated liver disease or
- if they are in acute withdrawal or before and during a planned medically assisted alcohol withdrawal.

Thiamine (Vitamin B1) should be given in doses toward the upper end of the BNF range.[35] Therefore, the recommended dose is 200 to 300 mg daily in divided doses.[1]

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 six 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 diet is inadequate or alcohol consumption is resumed.[34]

Offer prophylactic parenteral thiamine followed by oral thiamine to harmful or dependent drinkers:[35]

- if they are malnourished or at risk of malnourishment or
- if they have decompensated liver disease

and in addition

- they attend an emergency department or
- are admitted to hospital with an acute illness or injury.

Thiamine to treat suspected WE:

Offer parenteral thiamine to people with suspected WE. Oral thiamine treatment should follow parenteral therapy.[35] Anaphylaxis has been reported with parenteral B vitamins, therefore facilities for treating anaphylaxis (including resuscitation facilities) should be available when parenteral thiamine is administered.[36]

Vitamin B complex

Vitamin B complex preparations are considered by the Joint Formulary Committee to be less suitable for prescribing.[1] Consequently, they should not be considered as drugs of first choice but may be justifiable in certain circumstances. These include:

- medically diagnosed deficiency
- chronic malabsorption
- refeeding syndrome which consists of metabolic changes that occur on the reintroduction of nutrition to in those who are malnourished or in the starved state.[2]

The NICE clinical guideline on nutrition support in adults[26] 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 compound strong 1 or 2 tablets three times a day and a balanced multivitamin/ trace element supplement once daily.

Vitamin B compound strong should be prescribed in these circumstances rather than vitamin B compound as it represents better value for money – see Table 2.[34]

Table 2: Comparison of vitamin B complex preparations[1,5,27,37]

Preparation*	Ingredients	Indication	England and Wales - 28 day cost (£)	Scotland - 28 day cost (£)
Vitamin B compound tablets	Nicotinamide 15 mg Riboflavin 1 mg Thiamine hydrochloride 1 mg	Prophylaxis of deficiency in adults: 1–3 tablets daily	£26.63 – £79.89	Not included in the Scottish Drug Tariff
Vitamin B compound strong tablets	Nicotinamide 20mg Riboflavin 2mg Thiamine hydrochloride 5mg Pyridoxine hydrochloride 2mg	Treatment of deficiency in adults: 1–2 tablets 3 times a day	£4.05 – £8.10	£10.11-£20.22

*Listed in Part VIIIA of the England and Wales Drug Tariff or Part 7 of the Scottish Drug Tariff[5,27]

In England, the Regional Medicines Optimisation Committee (RMOC) position statement on oral vitamin B supplementation in alcoholism provides an overview of the appropriate prescribing of vitamin B preparations and suggested actions for commissioners and providers.[34] These include:

- Do not initiate vitamin B compound or vitamin B compound strong tablets for any of the following indications:
  - Prevention of 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.
- Review patients prescribed thiamine with a view to stopping if the patient has been abstinent for six weeks or more and has regained adequate nutritional status.
- Prescribe prophylactic oral thiamine 200 to 300mg 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.

Costs and savings

Approximately £94.5 million in England, £6.8 million in Wales and £10.2 million in Scotland is spent annually on the prescribing of vitamins and minerals [NHSBSA May-July21, and Public Health Scotland Apr-Jun21].

Patients who are being prescribed these preparations as dietary supplements or as a general "pick-me-up" should have their vitamin and mineral preparation discontinued and a healthy balanced diet or self-care with an OTC preparation should be recommended. **Prescribing 10% less would save £9.4 million in England, £681,918 in Wales and £1 million in Scotland in 12 months [NHSBSA May-July21, and Public Health Scotland Apr-Jun21].**

Approximately £21.2million in England, £2.2million in Wales and £2.5million in Scotland per year is spent on cyanocobalamin 50 and 100 microgram tablets [NHSBSA May-July21, and Public Health Scotland Apr-Jun21].

This accounts for 23%, 32%, and 25% of the total spend on vitamins and minerals in England, Wales and Scotland respectively. If 50% of prescriptions were reviewed and transferred to self-care this could save £10.6 million in England, £1.1 million in Wales and £1.3 million in Scotland in 12 months [NHSBSA May-July21, and Public Health Scotland Apr-Jun21].

Approximately £4.5million in England, £147,936 in Wales and £187,952 in Scotland is spent annually on vitamin B compound tablets. Changing these prescriptions to vitamin B compound strong tablets could save £450,199 in England, £14,586 in Wales and £22,191 in Scotland in 12 months [NHSBSA May-July21, and Public Health Scotland Apr-Jun21].

Summary of actions to consider

- Vitamins and minerals should only be prescribed for the management of actual or potential vitamin or mineral deficiency. They should not be prescribed as dietary supplements or a general 'pick-me-up' due to limited evidence of clinical effectiveness.
- Eating a healthy, varied, and well-balanced diet should be advised to provide the vitamins and minerals needed. Take the opportunity to remind all patients on the benefits of healthy eating. For example, using the resources described in this bulletin and in the template patient letter.
- Take the opportunity to ensure that all eligible pregnant women, women with a child under 12 months and children aged up to four years are aware of the NHS Healthy Start Scheme.
- Use the template clinical audit tools to ensure that the prescribing of these preparations is for the management of conditions which lead to actual or potential vitamin or mineral deficiency, and that the most cost-effective preparations are prescribed. Common examples of appropriate prescribing include oral thiamine for patients who are alcohol dependent and whose diet may be deficient, and cyanocobalamin for pernicious anaemia.
- If national prescribing criteria are met, ensure that:
  - The preparations prescribed are the most cost-effective.
  - All patients are reminded of the importance of healthy eating.
- If national prescribing criteria are not met:
  - Review and stop prescribing the preparation. Keep patients fully informed by using the template letter which advises patients to purchase an appropriate preparation OTC with the support of their community pharmacist. It also highlights the importance of, and describes the principles around healthy eating.
- For vitamin B preparations review all 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. Vitamin B compound strong tablets represent the most cost-effective preparation.
  - Prescribed prophylactic oral thiamine. For harmful or dependent drinkers, the prescribed dose should be 200 – 300mg daily on divided doses. If patients have been abstinent for 6 weeks or more and have regained adequate nutritional status, consider stopping treatment.

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Additional PrescQIPP resources

Briefing	https://www.prescqipp.info/our-resources/bulletins/bulletin-296-vitamins-and-minerals/
Implementation tools	
Data pack	https://data.prescqipp.info/?pdata.u/#/views/B296_Vitaminsandminerals/FrontPage?:iid=1

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