

## Vitamin D Prescribing Guidelines - Adults

### APC Position Statement on Vitamin D Supplements

Public Health England has advised that all adults should consider taking Vitamin D supplementation, especially in the winter months. The APC considers it appropriate that patients are asked to purchase low dose supplements for prevention of vitamin D deficiency or maintenance of vitamin D levels following high dose treatment.

Vitamin D blood levels should only be tested if the patient has symptoms indicative of rickets, osteomalacia or symptomatic hypocalcaemia, i.e. severe aching in bone AND muscles and proximal muscle weakness making standing up and walking difficult and painful, with marked waddling gait. If deficiency is found in the presence of these symptoms, a course of high dose replacement therapy should be prescribed as per the flowchart on [page 2](#).

### **Key content:**

**Treatment of Symptomatic Vitamin D Deficiency Flowchart – [page 2](#)**

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**Treatment of Symptomatic Vitamin D Deficiency in Adults in Primary Care**  
**EXCLUSIONS: eGFR<30ml/min, pregnancy, hyperparathyroidism – seek specialist advice**

Does the patient have **Symptoms** indicative of rickets, osteomalacia or symptomatic hypocalcaemia?

**YES**

**NO**

**Test Vitamin D levels + request bone profile**  
*Vitamin D Levels will naturally be lower October-March due to seasonal variation*

**It is NOT appropriate to request a test for vitamin D deficiency**

Levels low (<50nmol/l)

Levels adequate (≥50nmol/l)

Vitamin D deficiency (<25nmol/l)

Vitamin D insufficiency (25-49nmol/l)

Check Bone, liver, renal profile.  
 Consider checking PTH, TTG abs, immunoglobulins

**High strength Vitamin D replacement** <sup>3,6</sup>  
 Aim for cumulative dose of 300 000 units<sup>5</sup>

Currently available cost-effective, options for oral high dose replacement include:

- Hux D3\*<sup>^</sup> 20,000 capsules, **3 caps weekly** for 5 weeks (unlicensed) or
- InVita D3\* 50,000 units/ml oral liquid, 1 ampoule **weekly** for 6 weeks<sup>14</sup> or
- InVita D3 50,000 unit capsules, **1 weekly** for 6 weeks.

\*suitable for vegetarians ^ Nutritional supplement

**Natural ways to maintain vitamin D levels:**

**Dietary sources:**

- Eat more oily fish, cod liver oil and other fish oils.
- Eat egg yolk, fortified cereals, yoghurts and margarine. These are some foods fortified with vitamin D.

**Safe sun exposure:**  
 For Vitamin D synthesis, little and often is best. In the UK, two or three short sunlight exposures per week April-September are sufficient to achieve adequate Vitamin D levels. In winter the body relies on tissue stores.

**OTC products:**  
 Low-strength (≤1000 units) Vitamin D supplements are available to buy over the counter.

**Maintenance supplementation**  
 800-1000 units per day (for purchase)

**Advise patient to purchase supplement containing colecalciferol 800-1000 units.**

**For full prescribing details, refer to [page 6](#) or product SPCs [www.emc.medicines.org.uk](http://www.emc.medicines.org.uk)**

Check calcium levels 1 month after high dose replacement. Recheck vitamin D levels 6 months after high dose replacement.<sup>3</sup>

## Guidance on the management of vitamin D deficiency and insufficiency states in adults in primary care

**SCOPE:** This guidance is currently limited to the management of vitamin D deficiency or insufficiency states in adults. The document does not currently cover management of low vitamin D levels in children, or in more complex or specialist clinical situations such as hyperparathyroidism, Paget's disease, severe renal impairment (eGFR <30ml/min), or for indications such as vitamin D deficiency in pregnancy. For advice on management of vitamin D deficiency in children, please refer to the local guideline on management of Vitamin D Deficiency in Children. The document will be reviewed frequently to reflect the rapidly evolving nature of literature on the subject.

**AIMS:** There are three principal aims. These are to provide:

- A logical and structured approach to the management of Vitamin D deficiency in adults.
- An integrated approach to management of vitamin D deficiency between primary and secondary care.
- Practical advice about dosing regimens and available products.

### BACKGROUND

#### Vitamin D and bone health

Vitamin D is essential for musculoskeletal health. It promotes calcium absorption from the bowel and enables mineralisation of newly formed osteoid tissue in bone. NICE estimate that around 8-24% of adults may have low vitamin D status, which the Scientific Advisory Committee on Nutrition ([SACN](#)) recently defined as being 25nmol/L (the concentration below which risk of poor musculoskeletal health is increased).<sup>(1)</sup>

#### Natural sources of vitamin D

Synthesis of vitamin D from sunlight becomes effective from March with maximum concentrations observed in September after a summer of exposure. Safe sun exposure during the summer months is vital to ensure adequate stores of vitamin D over the winter months. The [NICE guidance on safe sun exposure](#) suggests that *most people* can go out in the sun for short periods (less than the time it takes for the skin to redden or burn) of time in April to mid-October and expose forearms, lower legs, hands and face to make sufficient vitamin D. People with darker skin may need longer periods of exposure to make sufficient vitamin D. Sunlight is the main source of natural vitamin D but dietary sources also provide vitamin D, including oily fish such as salmon and mackerel, egg yolks and fortified food such as cereals, yoghurt and margarine. Most people, with some lifestyle modification, should be able to maintain adequate vitamin D through safe sun exposure or via their diet. Vitamin D supplements are widely available to purchase.<sup>(1-4)</sup>

#### Signs and symptoms of vitamin D deficiency

People with vitamin D deficiency may have a history of fragility fractures, evidence of radiological osteopenia, skeletal abnormalities and/or abnormal biochemistry (raised ALP/PTH, low calcium, phosphate). Unfortunately, subjective symptoms of vitamin D deficiency are vague and non-specific. Patients with clinically relevant vitamin D deficiency may present with severe aching bones and muscles with proximal muscle weakness (which makes standing/walking difficult and painful) and marked waddling gait.<sup>(2,3)</sup>

#### Deciding whether to test for vitamin D deficiency

There is no sound rationale which supports testing of vitamin D levels in patients for any medical condition other than suspected bone disease (in the presence of risk factors). Some clinicians have tested patients because of non-specific complaints such as tiredness. Such requests are inappropriate given that there is no clinical evidence to support treatment of these complaints with vitamin D.

A Viewpoint article in the JAMA (5) discussed vitamin D screening and supplementation for non-skeletal health benefits and concluded that *'When there is uncertainty about whether supplementation is warranted, the usual medical principle is to err on the side of caution and to avoid excess. Thus, while awaiting the results of the large trials now in progress, physicians would be well advised to follow current US Preventive Services Task Force (USPSTF) and US Institute for Optimum Nutrition (ION) recommendations and avoid over screening and overprescribing supplemental vitamin D. Doing so is not only in the best interest of current patients but will also help advance knowledge to benefit future patients and inform future public health recommendations.'*<sup>(1-5)</sup>

#### Evidence for treating vitamin D deficiency

In the past, low vitamin D levels would principally have been associated with musculoskeletal conditions such as Osteomalacia. However, there is an ever increasing amount of observational literature published which investigates the use of vitamin D in various chronic diseases (e.g. autoimmunity, cancer, diabetes, and cardiovascular outcomes), often with unclear, tenuous or surrogate endpoints.<sup>(6-10)</sup> To further complicate the issue, media reports continue to suggest vitamin D as a panacea for chronic disease. Data supporting these associations originate from prospective

observational studies and interpretation of observational data is complex because associated risk factors may cause, rather than be a consequence of, low circulating vitamin D.<sup>(8)</sup> Despite publication of numerous systematic reviews and meta-analyses, there remains no convincing evidence of a clear role for vitamin D for any of these chronic disease states.<sup>(6-10)</sup> NICE recognises only that vitamin D deficiency states affect bone growth and development.<sup>(2)</sup> More recently, SACN suggests that there may be some clinically relevant evidence to suggest that vitamin D supplementation may improve muscle function and reduce the risk of falls in adults who are deficient in vitamin D.<sup>(1)</sup>

**GUIDANCE:** The National Osteoporosis Society (NOS) issued a practical guide called “*Vitamin D and Bone Health: A Practical Clinical Guideline for Patient Management*”<sup>(3)</sup> upon which this guidance is based. This local guidance seeks to address inconsistencies in practice and to guide choice of cost effective vitamin D products which are suitable for variable patients’ needs.

Oral vitamin D3 (colecalfiferol) is recommended over other forms of vitamin D (e.g. ergocalciferol) by NOS. It is synthesised in the skin through the action of ultraviolet light on 7-dehydrocholesterol. Risk factors for developing low vitamin D levels include limited exposure to sunlight (e.g. those living in the Northern Hemisphere during winter months, those who cover large areas of skin when outdoors or habitually use sun block, darker skinned people), a vegan or vegetarian diet, malabsorptive diseases and other factors.<sup>(1, 3-11)</sup>

**Box 1: Sources of vitamin D** <sup>(2-8)</sup>

- Sources of Vitamin D:**
- UVB radiation from the sun
  - Oily fish such as salmon, sardines, herring, mackerel, trout, fresh tuna
  - Cod liver oil and other fish oils
  - Egg yolk
  - Fortified cereals
  - Margarine

**Box 2: Risk Factors** <sup>(2-8)</sup>

- Risk Factors (Adults)**
- Pigmented skin tone, lack of sun exposure
  - Institutionalised, elderly or obese
  - Malabsorption, short bowel syndrome, cholestatic liver disease, coeliac disease
  - Non-fish eating diet
  - Use of anticonvulsants, rifampicin, cholestyramine, HAART, glucocorticoids.

**1. Diagnosis of low vitamin D levels (deciding which patients to test)**

Serum vitamin D levels should NOT be checked routinely and clinicians should actively avoid costly measurement of vitamin D levels in asymptomatic patients who are not suspected to have bone disease. Testing of serum vitamin D levels in winter months (October to March) will result in naturally lower levels due to seasonal variation. Levels should only be checked when a patient has symptoms that suggest rickets, osteomalacia, or symptomatic hypocalcaemia (Box 3).<sup>(1-3)</sup>

**Box 3: Which patients to test for vitamin D deficiency**

- Specific SYMPTOMS** which may lead to testing of vitamin D levels if clinically appropriate
- **Severe aching in bone and muscles and proximal muscle weakness making standing up and walking difficult and painful. Marked waddling gait**

In all other cases, where the patient has risk factors for deficiency (Box 2), the clinician should provide lifestyle advice.<sup>(2)</sup> NHS information is available [here](#) and a Coventry and Rugby CCG leaflet ‘Vitamin D Information’ is available [here](#) – they include advice about safe exposure to sunlight as well as diet and supplements to maintain adequate vitamin D naturally.

**2. Requesting tests for vitamin D deficiency (what to test for)**

Once clinicians have decided which patients need to be tested for vitamin D deficiency, they should request a test for 25-hydroxyvitamin D (25-OHD) levels which represent serum concentration of vitamin D3. Clinicians may also choose to test serum calcium, phosphate, alkaline phosphatase and parathyroid hormone levels (bone profile) when diagnosing the condition and at their discretion thereafter.<sup>(3, 5-7)</sup>

**3. Interpreting vitamin D levels (what do the test results mean)**

Locally, a vitamin D level of less than 25nmol/L is defined as deficient, and treatment is recommended. A serum level of 25-50nmol/L may be adequate in some people; however, in patients presenting with symptoms as listed in Box 3, treatment is advised. A serum level of greater than 50nmol/L is sufficient for almost the whole population but lifestyle advice (see links to leaflet above) may be beneficial.<sup>(1,2,2a)</sup>

Box 4: Local interpretation of vitamin D levels <sup>(1-3)</sup>

Deficient: < 25nmol/L  
 Insufficient: 25-50nmol  
 Adequate: > 50nmol/L  
 \*Levels represent serum concentration of 25-hydroxyvitamin D (25-OHD)

**4. Treatment of symptomatic vitamin D deficiency in adults**

- The primary aim of treatment is to replenish vitamin D stores then continue with a lower maintenance dose of vitamin D.<sup>(3)</sup>
- The NOS Guideline on Vitamin D and Bone Health recommends an oral loading regimen of vitamin D3 (colecalfiferol) for treatment of deficiency up to a total of approximately 300,000 units vitamin D given either as weekly or daily split doses. This is described in the NOS guidance as a cumulative dose.<sup>(3)</sup>
- This can be followed with a maintenance phase which involves giving 800 to 2000 units of oral vitamin D3 (colecalfiferol) daily or larger doses at less frequent intervals (see Table 1). The exact regimen will vary depending on the local availability of vitamin D products. There is still no clear consensus on how long the maintenance phase should last. It would be reasonable to continue the maintenance regimen for as long as it is deemed necessary in the clinical judgement of the prescriber; this may involve assessment of whether lifestyle changes have been implemented and/or checking serum vitamin D levels.<sup>(3)</sup>

**5. Monitoring vitamin D levels during treatment**

Vitamin D levels do not need to be checked routinely, and can take 3-6 months to reach a steady state after treatment has started. Local specialists recommend re-checking vitamin D levels 6 months after a loading regimen of vitamin D has been given. If levels are still sub-optimal, compliance with medication should be discussed. Alternatively, consider referral to an appropriate specialist.<sup>(3)</sup>

Calcium levels should be checked 1 month after the final loading dose of vitamin D has been taken; this is in order that patients with sub-clinical primary hyperparathyroidism are detected. Providing an oral loading regimen of vitamin D is unlikely to cause hypercalcaemia but if concerned, clinicians should consider checking calcium levels as they are a more appropriate indicator of toxic levels of vitamin D. Should unexplained nausea and/or vomiting develop in a patient taking pharmacological doses of vitamin D, consider checking calcium levels.<sup>(3)</sup>

**6. Choice of vitamin D products**

There are several licensed high-dose vitamin D products available. In line with MHRA guidance, it is advised that prescribers use these licensed products wherever possible. A licensed injection of ergocalciferol 300,000 unit is also available.<sup>(12)</sup> However, it is not recommended by NOS due to concerns about its usefulness. As well as being a painful injection, its absorption is thought to be poor. Also, annual depot vitamin D therapy, either by intramuscular injection or orally, is not recommended as it has been suggested that it is ineffective and may increase fracture risk. Therefore, use of this injection is only recommended when there is concern regarding oral absorption (e.g. extensive bowel resection).<sup>(3)</sup>

**Table 1: Coventry and Warwickshire treatment guidelines, based on expert consensus:**

Serum Vitamin D (25-OHD) level	Diagnosis and management strategy	Licensed colecalciferol product to use	Treatment dose and frequency	Cost
50-74nmol/L	<b>Adequate:</b> Lifestyle advice	Lifestyle advice. Consider over the counter supplement.		N/a
25-50nmol/L (with symptoms of bone disease)	<b>Insufficiency:</b> High dose treatment course followed by long term maintenance	<i>Any of:</i> <b>Hux D3 20,000</b> unit capsules	<b>3 caps weekly</b> for 5 weeks	£1.31 (5 week course)
Less than 25nmol/L (with symptoms of bone disease)	<b>Deficiency:</b> High dose treatment course followed by long term maintenance	<b>InVita D3 50,000</b> units/ml oral liquid	<b>1 ampoule weekly</b> for 6 weeks	£12.50 (6 week course)
		<b>InVita D3 50,000</b> unit capsules	<b>1 cap weekly</b> for 6 weeks	£10 (6 week course)
<b>Maintenance therapy</b>	<i>Advise patient to <b>purchase</b> over the counter supplement containing 800 to 1000 units daily.</i>			

**Table 1** represents the recommended options for the management of low vitamin D. These recommendations are made based on the products available at the time of revision of this document; however it is recognised that new licensed products are being launched regularly. These will be evaluated at each revision of this guidance.

Notes:

- Vitamin D supplements should be taken with food to aid absorption<sup>(3)</sup>
- Dose conversion: dose of vitamin D in micrograms can be calculated by dividing the number of international units by 40<sup>(3)</sup>
- All prices consistent with latest BNF prices at time of revision of document.

## 7. Practical information on products:

Full prescribing information is available in the Summary of Product Characteristics (SPC) for each product via [www.medicines.org.uk](http://www.medicines.org.uk)<sup>(14,16,17)</sup> Oral products should be prescribed by brand name where possible.

### Recommended licensed vitamin D preparations:

- **Hux D3** is a nutritional supplement containing 20,000 units per capsule. Colecalciferol is derived from live sheep wool fat so it is suitable for vegetarians but not vegans.<sup>(15,16)</sup>
- **Invita D3 50,000 unit soft capsules** are licensed. The capsule shell is made from bovine gelatine so it is not suitable for vegetarians or vegans. They do not contain peanut or soybean oil.<sup>(15,17)</sup>
- **InVita D3 oral solution** is available in 1ml ampoules. Each ampoule contains 25,000 units or 50,000 units colecalciferol. The contents of the ampoule should be emptied into the mouth and swallowed or emptied onto a spoon taken orally. It can also be taken by mixing the ampoule contents with a small amount of cold or lukewarm food immediately prior to use.<sup>(14)</sup> The colecalciferol is derived from live sheep's wool fat<sup>(15)</sup> and the company states that this product is suitable for vegetarians.

### Licensed Injection:

- **Ergocalciferol IM injection** is licensed for the treatment of vitamin D deficiency. However, use of the IM injection is only recommended when there is concern regarding oral absorption (e.g. extensive bowel resection). Dosages should be individualised for each patient. Usually 300,000 units is given as a single dose and repeated if necessary after 3-4 months, depending on clinical response and requirements.<sup>(12)</sup> If the injection is used, close monitoring of serum and urinary calcium, phosphate and renal function is needed to avoid hypercalcaemia.<sup>(12)</sup>

### Other preparations:

- **For vegans**, vitamin D2 (ergocalciferol) products which are derived from plants will be most suitable.<sup>(15)</sup> However, prescribers will also need to check the formulation of the product (e.g. some ergocalciferol products will be formulated in a gelatine capsule, which will be unacceptable to vegans). For further advice on this please contact the Medicines Optimisation Team.
- **Short acting potent analogues of vitamin D such as alfacalcidol or calcitriol** should NOT be used in this situation because there is no evidence to support efficacy and they can lead to hypercalcaemia.<sup>(3)</sup>

## 8. Patient Information

- NHS information is available [here](#).
- A Coventry and Rugby CCG leaflet 'Vitamin D Information' is [here](#).

## 9. Requests from Secondary Care

- Where a consultant has tested vitamin D levels in line with APC guidance and deficiency is found, they may request that the GP prescribe a course of high dose colecalciferol replacement. However, if testing is outside of this guidance, and follow up is required in primary care, it is the GP's decision whether prescription of high dose therapy or purchase of OTC supplementation is appropriate. For further advice contact the Medicines Optimisation team.
- Where high dose vitamin D is prescribed on discharge from an inpatient stay, the full quantity to complete the course should be supplied to avoid potential confusion.

## 10. Role of calcium supplements

If vitamin D is prescribed as an oral loading regimen, as maintenance therapy or as supplements, then consideration ought to be given to whether enough calcium is included in the diet. **Calcium supplements and combined calcium and vitamin D combined supplements are not routinely indicated in patients with low vitamin D3 levels unless the patient also has hypocalcaemia.**<sup>(2)</sup> This is because the calcium component may be unnecessary and can reduce compliance due to unpalatability. Serum calcium levels should, however, be monitored as described.

If hypocalcaemia is found, then the first step in managing it is to advise higher dietary intake of calcium. Calcium calculators (e.g. <http://www.cgem.ed.ac.uk/research/rheumatological/calcium-calculator>) can help clinicians to do this. If patients with osteoporosis or bone disease are found to not be reliably consuming at least 700 mg of calcium each day, then calcium supplementation alongside vitamin D should be considered. In these cases, combination products of calcium and vitamin D may be helpful for compliance but the strength of vitamin D is often too low and their use limits flexibility in dosing.<sup>(3)</sup>

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## Disclaimer

Statements made by manufacturers regarding the terms 'halal' or 'kosher' have been omitted from this guideline. Individuals' religious belief systems are known to vary considerably and the authors of this guideline cannot broadly advise on the religious acceptability of products. To support patients and healthcare professionals in selecting an acceptable product, manufacturers contact details can be supplied so that individuals are able to find out whether the products comply with their individual belief system. Clinicians who wish to find out more about the terms 'halal' in relation to medicines use may wish to refer to the UKMI Q&A document on this.