# South East London Clinical Guideline for the Management of Vitamin D Insufficiency and Deficiency in ADULTS – Excluding CKD stage 4 and above

***This guideline does not cover the management of vitamin d insufficiency and deficiency in people with chronic kidney disease (CKD) stage 4 and above****. This document is for guidance only and not intended to replace the health professional's clinical judgement for individual patients. The South East London Integrated Medicines Optimisation Committee has separate guidance for* management of Vitamin D deficiency and insufficiency in children.

## 1. Introduction

Vitamin D is essential for musculoskeletal health as it promotes calcium absorption from the bowel: enables mineralisation of newly formed osteoid tissue in bone and plays an important role in muscle function [1]. The term 'vitamin D' generally refers to two very similar molecules. Vitamin D3, also known as colecalciferol, is the most abundant in humans and is produced in the skin following exposure to sunlight [1]. Vitamin D2, or ergocalciferol, occurs naturally in some mushrooms and yeast. The amount in most vegetables is negligible.

The body converts both forms of vitamin D to 25-hydroxyvitamin D (25(OH)D). Tests to assess vitamin D status measure levels of 25(OH)D in the blood. 25(OH)D is itself converted in the kidney to the biologically active form 1,25-dihydroxyvitamin D, also known as calcitriol.

The main manifestation of vitamin D deficiency is osteomalacia in adults, which is generally associated with a serum 25(OH)D concentration of less than 25nmol/L [2]. There is a growing understanding of the importance of vitamin D in terms of its potential role in the prevention of non-skeletal disorders such as auto-immune disease, cancer, mental health problems and cardiovascular disease.

## 2. Purpose and Scope

This document is a South East London-wide guideline broadly based on the Royal Osteoporosis - Better bone health for everybody [1] and the Clinical Knowledge Summaries (CKS) [2].

**Before using this guidance refer to a specialist for advice if the patient has:**

1. A diagnosis of stage 4 and above CKD
2. A history of renal stones or sarcoidosis
3. Hypercalcaemia / hyperparathyroidism

**Vitamin D supplementation during winter: PHE and NICE statement 2020[4]**

Public Health England and NICE [3] recommends that ALL people should consider buying a daily supplement over the counter (OTC) containing 10micrograms (mcg)/400 International Units (IU) of vitamin D in autumn and winter (October to early March). At risk groups should take daily supplements all year round.

**Adults who are at higher risk of vitamin D deficiency include people** [2]:

- Aged 65 years and over.
- Who have low or no exposure to the sun, for example those who cover their skin for cultural, religious, or health reasons; who are housebound; or who are confined indoors for long periods.
- Who have darker skin pigmentation, for example people of African, African-Caribbean, or South Asian origin, etc.
- With a gastrointestinal or malabsorption disorder, or following weight loss surgery, resulting in a reduced ability to absorb fat-soluble vitamin D.
- With severe liver disease or end-stage chronic kidney disease (CKD).
- Taking certain drugs that increase the risk of vitamin D deficiency (see Section 9 for details)
- Are pregnant or breastfeeding, due to the risk of foetal neonatal hypovitaminosis.
- Are obese (body mass index greater than 30 kg/m$^2$) – vitamin D may be sequestered into adipose tissue reducing bioavailability.



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## 3. Treatment of Vitamin D Deficiency

**Flow Chart 1: Management of Vitamin D levels in adults over 18 years of age (Excluding CKD 4 and above)**
*Routine testing* for 25 hydroxyvitamin D level is not recommended

**Patient with high risk factors of vitamin D deficiency**

NO → Public Health England and NICE 2020
From October to March, **EVERYONE** should consider taking a daily supplement containing 10 micrograms (400 units) of vitamin D for prevention, to help keep bones, teeth and muscles healthy. This can be purchased **over the counter (OTC)**.

YES

**Does the patient have SYMPTOMS indicative of rickets, osteomalacia or hypocalcaemia?**
Clinical features of vitamin D deficiency include musculoskeletal symptom such as:

- Muscle pain
- Proximal muscle weakness
- Rib, hip, pelvis, thigh and foot pain are typical.
- Fractures

Raised alkaline Phosphatase (ALP) – can be found in liver function blood test
- may indicate more severe osteomalacia.

NO → **Routine replacement / maintenance therapy self-care only**

- Give **lifestyle advice** NHS patient information on Vitamin D: Vitamin D - NHS (www.nhs.uk)
- Recommend OTC **oral colecalciferol 800-2000 units daily suitable year-round** to be initiated one month after loading dose completed, **for example.**

**Valupak D3 1,000 units tablets (Cost price: £0.59/60 tablets)**
**Patient to purchase OTC for approx. <£2.00 (2 months supply)**

**prescribe** Stexerol-D3® 1,000 unit tablets **ONLY for patients with conditions exempt from NHSE self-care directive** (NHS SEL ICB self- care leaflet )

- **Assess** the person's need for **calcium supplementation**. To assess the person's dietary calcium intake. Consider using an online calcium calculator, such as the UK Centre for Calcium Genomic and Experimental Medicine (CGEM) calculator: CGEM Calcium Calculator (ed.ac.uk).

**TEST for vitamin D levels and bone profile**
Moderate to severe symptomatic hypocalcaemia is a medical emergency and will need acute admission and treatment. Refer to specialist if CKD 4.

| **Deficient** | **Insufficient** | **Sufficient** |
|---|---|---|
| **<25nmol/L (<10mcg/L)** | **25-50nmol/L (10-20 mcg/L)** | **>50nmol/L (>20 mcg/L)** |

**Loading dose: Prescribe as ACUTE items.** (No licensed product for Vegan, see section 5.3 for details):

| | BNF Product Choice | Recommended Dosage | Halal/Kosher | Vegetarian |
|---|---|---|---|---|
| 1st Line | Invita® D3 50,000 unit capsules | One cap weekly for 6 weeks | Y | N |
| Alternative | Stexerol® D3 25,000units tablets | Two caps weekly for 6 weeks | Y | Y |
| Pregnant & Breastfeeding women | Thorens® 10,000iu/ml oral solution | 0.4mls (20 drops – 4000iu) daily for 10 weeks (Unlicensed dose agreed by GSTT/KCH) | Y | Y |

(Total of approximately 300,000 units colecalciferol per treatment course)

**Primary Care**: Prescribe by brand to ensure a licensed product or preparation suitable for specific patients (e.g. vegetarians) is dispensed (refer to **Appendix I for all licensed preparations**).

**Secondary care only :** off-label rapid daily dosing might be considered e.g. Colecalciferol 20,000iu bd for 7 days

*If patient cannot tolerate oral preparation/severe gastrointestinal malabsorption*
IM injection: **1 injection** of 300,000 units ergocalciferol (for specialist initiation only)

YES → **Monitoring**: check serum calcium levels 4 weeks after loading dose, in case primary hyperPTH is unmasked, check vitamin D level at 12 weeks to allow level to plateau

NO → **Check adherence, consider specialist advice/referral.**

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## 4. When to test for Vitamin D deficiency

NICE [3] recommends that health professionals should ***NOT** routinely test* vitamin D in people unless:

- they have symptoms of vitamin D deficiency e.g. chronic widespread pain with other features of osteomalacia (such as proximal muscle weakness)
- there is a clinical need e.g. suspected bone disease such as osteomalacia/osteoporosis, known bone disease, where correction of vitamin D deficiency is needed prior to specific treatment [2]. e.g. starting patients on a potent antiresorptive agent (zoledronate or denosumab or teriparatide)

## 5. Consideration for specific cohort of patients

### 5.1 Pregnant and Breastfeeding Mothers

Adequate vitamin D intake may be difficult to achieve with diet alone, and pregnant women are advised to buy over the counter vitamin supplements or signposted to Healthy Start scheme or any similar scheme.

Healthy Start Women's vitamin tablets are supplied free of charge to pregnant and breastfeeding women who are eligible beneficiaries under the Healthy Start government led scheme. [4] Healthy Start Women's vitamin tablets contain 70 milligrams of vitamin C, 10 micrograms (400 units) of vitamin D and 400 micrograms of folic acid. For more information, please visit www.healthystart.nhs.uk

- **Prescribing for vitamin D deficient pregnant women** [5]

  There is currently no UK guidance on managing vitamin D deficiency in pregnancy. International guidance recommends a daily intake of 1,000-2,000units, with upper limits of 4,000units daily advised in the American College of Obstetricians and Gynaecologists (ACOG) guidelines. A new born baby's vitamin D status is largely determined by the mother's level of vitamin D during pregnancy.[3]

  The decision to treat vitamin D deficiency should be based on local laboratory findings and be guided by local vitamin D reference ranges.

  The ACOG make no recommendations in their guidance around monitoring of serum calcium or vitamin D levels following treatment with vitamin D in pregnancy. In certain situations, higher doses may be used or recommended by specialists.

- **Managing vitamin D deficiency in breast feeding women**

  Higher doses of vitamin D for treating deficiency may be considered in a pregnant woman if local laboratory results indicate a need for treatment.

For further information on the use of vitamin D during pregnancy, please visit bumps - best use of medicine in pregnancy, Vitamins, minerals and supplements in pregnancy NHS (www.nhs.uk), Healthy eating and vitamin supplements in pregnancy patient information (rcog.org.uk)

### 5.2 Care homes

Care home providers are required to meet resident's full nutritional needs to sustain life and good health, and reduce the risks of malnutrition, in line with regulation 14 (Part A) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014[6] and advice from the Care Quality Commission (CQC). In addition to provision of nutritious meals, this should include food supplements where necessary, such as vitamin D.

Vitamin D deficiency in care home residents should be managed the same way as according to flowchart 1.

### 5.3 People with diet or cultural requirements

Information on choosing an oral vitamin D preparation for vegetarians or vegans and choosing a suitable product for patients with a soya or peanut allergy is available.

# 6. Natural ways of increasing Vitamin D levels

## 6.1 Safe Sun exposure

Sun exposure is the main source of vitamin D and this should be balanced with the risks of excessive exposure. Sunburn should always be avoided. Little and often sun exposure is best for vitamin D synthesis. On 21st July 2016, Public Health England issued new guidance on vitamin D based on the recommendations of the Scientific Advisory Committee on Nutrition. The advice notes that vitamin D is made in the skin on exposure to UVB in sunlight and that in spring and summer, the majority of the population get sufficient vitamin D through sunlight on the skin and a healthy, balanced diet. However, since it is difficult to quantify, a daily dietary intake of 10 micrograms equivalent to 400 international units (IU) is recommended for everyone particularly in the autumn and winter months.

Individuals from ethnic minority groups with dark skin, e.g. from African, Afro-Caribbean and South Asian backgrounds etc, may not get enough vitamin D from sunlight in the summer and therefore should consider taking a supplement all year round.

Following Public Health England advice, prescribing of vitamin D purely for supplementation should be avoided and patients/parents/carers should be requested to purchase vitamin D over the counter.

Unprotected sun exposure should be avoided in patients with the following conditions: sensitive skins, skin cancer, porphyrias, xeroderma pigmentosum, albinism, granulomatous disease (sarcoid but not tuberculosis) and lymphoma.

Unprotected sun exposure should also be avoided in patients who are taking the following medications: sulphonamides, phenothiazines, tetracyclines, quinolones, psoralens, isotretinoin or any other photosensitising medications.

## 6.2 Dietary advice

Please refer to the NHS choices website on vitamin D for sources of dietary vitamin D (Vitamin D - NHS (www.nhs.uk)).

# 7. Requirements for monitoring vitamin D levels[3]

| Status | Monitoring Advice |
|---|---|
| High risk patients<br>(no symptoms) | Routine monitoring of plasma 25(OH)D is generally unnecessary. Advice to buy Vitamin D supplement (800 – 2000iu) daily OTC. |
| Symptomatic patients | Monitoring may be appropriate in patients with symptomatic vitamin D deficiency or malabsorption and where poor compliance with medication is suspected.<br>Symptoms indicative of rickets, osteomalacia or hypocalcaemia<br>• Muscle pain<br>• Proximal muscle weakness<br>• Rib, hip, pelvis, thigh and foot pain are typical.<br>• Fractures<br>Raised alkaline Phosphatase (ALP) may indicate more severe osteomalacia |
| Post treatment dose | Check adjusted calcium within 1 month after the administration of the last loading dose to detect those with primary hyperparathyroidism. If hypercalcaemia is detected stop further vitamin D supplementation and investigate |

Note: specialists may recommend specific vitamin D treatments outside of this guideline for specific patient cohorts e.g. patients with CKD stage 4 and above therefore GPs may be requested to carry out specific monitoring.

Routine monitoring of 25(OH)D is clinically unnecessary, but may be appropriate if:

a) symptoms of vitamin D deficiency continue.
b) malabsorption is suspected (may need advice from or referral to a specialist)
c) poor compliance with medication is suspected

It takes at least 3-6 months to achieve steady state levels of 25(OH)D therefore do not routinely check levels before this. If there is no improvement clinically or in 25(OH)D status and the patient is compliant with the loading regimen, refer to a specialist [2]

## 8. Vitamin D toxicity

Vitamin D toxicity is rare. The Food and Nutrition Board of the Institute of Medicine [7] has summarised the evidence from a few studies of vitamin D [5], which covered a range of doses (800 to 300,000 units/day) and duration (months to years). It concluded that vitamin D below 10,000 units/day is not usually associated with toxicity, whereas doses equal to or above 50,000 units/day for several weeks or months are frequently associated with toxicity, including documented hypercalcaemia.

Excessive intake of vitamin D can lead to hypercalcaemia and its associated effects including apathy, anorexia, constipation, diarrhoea, dry mouth, headache, nausea, vomiting, thirst, and weakness. Later symptoms are often associated with calcification of soft tissues and include bone pain, cardiac arrhythmias, hypertension, renal damage, psychosis (rare) and weight loss.

Patients with blood levels more than 374 nmol/L are clinically considered to have Vitamin D toxicity. If toxicity is suspected, vitamin D must be withdrawn, hydration should be assessed (serum calcium and renal function are to be checked urgently), since emergency inpatient care with rehydration is usually indicated. If the person is taking calcium supplements, advise them to stop.

Dosage should be individualised for each patient based on indication, patent specific parameters and response (Clinicians are to pay attention to check whether a recent loading dose has been prescribed before prescribing loading dose). There is a wide range of doses used for different clinical indications and a number of different treatment regimens recommended in literature. Treatment regimens include both daily, weekly and monthly administration frequencies. However, most licensed products stated that the dose should not exceed 4,000 units/day or equivalent weekly [40,000 units/week] or monthly dose therefore more than 10,000 units/day is off-label use and should not be recommended to continue in primary care unless a robust monitoring mechanism is available.

For further information, please refer to Safety considerations when using Vitamin D – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice.

## 9. Potential drug interactions associated with vitamin D [2]

Clinicians are to adjust dosage and recheck serum Vitamin D level sooner (2-4 weeks), or seek specialist advice as appropriate during concurrent treatment with these drugs:

| | |
|---|---|
| Some antiepileptic drugs (carbamazepine, phenytoin, or barbiturates) | These can increase the metabolism of vitamin D, leading to a reduction in the effects of vitamin D.<br>Higher doses of vitamin D may be needed |
| Cardiac glycosides | Excessive dosing of vitamin D can induce hypercalcaemia, which may enhance the effects of digoxin and other cardiac glycosides (leading to an increased risk of digoxin toxicity and serious arrhythmias).<br>Close monitoring (and possibly a dose reduction of vitamin D) is needed during concurrent use. |


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| | |
|---|---|
| Corticosteroids | May increase vitamin D metabolism and elimination.<br>Higher doses of vitamin D may be needed. |
| Ion exchange resins (such as colestyramine) or laxatives (such as paraffin oil) | May reduce the gastrointestinal absorption of vitamin D.<br>Higher doses of vitamin D may be needed. |
| Ketoconazole, miconazole, and clotrimazole | These drugs are predicted to decrease exposure to vitamin D.<br>Higher doses of vitamin D may be needed. |
| Orlistat | May prevent the absorption of vitamin D, even in people also taking multivitamins.<br>Advise that vitamin D preparations should be taken at least 2 hours after taking orlistat. It may be necessary to monitor vitamin D levels, even if multivitamins are given. |
| Thiazide diuretics (such as bendroflumethiazide, indapamide, and metolazone) | May reduce the urinary excretion of calcium thereby increasing the risk of hypercalcaemia.<br>Close monitoring (and possibly a dose reduction of vitamin D) is needed during concurrent use. |

## 10. References


1. Royal Osteoporosis Society (ROS) Vitamin and Bone Health Guideline 2020 - A Practical Clinical Guideline for Patient Management
2. NICE Clinical Knowledge Summaries. Vitamin D deficiency in adults - treatment and prevention. Last revised January 2022. Available via https://cks.nice.org.uk/topics/vitamin-d-deficiency-in-adults/
3. NICE Clinical Guideline [PH56]. Vitamin D: increasing supplement use among at-risk groups. November 2014, available via https://www.nice.org.uk/guidance/ph56
4. https://www.healthystart.nhs.uk/
5. Specialist Pharmacy Service: Dosing and monitoring for treatment of Vitamin D deficiency in pregnancy. Last updated December 2021. Available on https://www.sps.nhs.uk/articles/dosing-and-monitoring-for-treatment-of-vitamin-d-deficiency-in-pregnancy/
6. Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 - regulation 14 (Part A). The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (legislation.gov.uk)
7. IOM (Institute of Medicine). Dietary reference intakes for calcium and vitamin D. Washington: DTNAP; 2011
8. https://www.gov.uk/government/publications/vitamin-d-for-vulnerable-groups/vitamin-d-and-care-homes-guidance#identifying-which-residents-should-take-vitamin-d-supplements

# Appendix I

| Name of Licensed product | Treatment Dose | Vegetarian | Halal/Kosher |
|---|---|---|---|
| **First line Invita® D3 50,000 unit capsules** | **50,000units/ week for 6 weeks** | **No (gelatine capsule)** | **Yes** |
| **First line for vegetarians Stexerol® D3 25,000units tablets** | **50,000 units/weeks for 6 weeks** | **Yes** | **Yes** |
| Colextra® D3 20,000unit capsules | 40,000units/ week for 7 weeks | No (gelatine capsule) | Unknown |
| Strivit® D3 20,000unit capsules | 40,000 units/week for 7 weeks | No (gelatine capsule) | Yes |
| Invita® D3 25,000unit capsules | 50,000units/ week for 6 weeks | No (gelatine capsule) | Yes |
| Colextra® D3 25,000unit tablets | 50,000units/ week for 6 weeks | Yes | Yes |

## Pregnant & Breastfeeding Patients

| Name of product | Treatment Dose | Vegetarian | Halal/Kosher |
|---|---|---|---|
| **Thorens® 10,000iu/ml oral solution** | **0.4mls (20 drops – 4000iu) daily for 10 weeks** (unlicensed dose agreed by GSTT/KCH) | **Yes** | **Yes** |

**Note:** Manufacturers may change the formulation of their products or the suppliers of the excipients and cannot guarantee products may come into contact with allergens during transit. The current status of the peanut or soya content of the product should therefore be obtained from the manufacturer.
Halal or kosher certification is dependent on information supplied by product manufacturers and may be subject to change. It is recommended that individuals verify information on each product with the manufacturers, it would remain the patient's decision as to whether the ingredients are acceptable under their vegan/vegetarian dietary guidelines.
The information and pricing in this guidance is correct at the time of publishing.


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