

## **South East London clinical guidance for the management of vitamin D deficiency and insufficiency in infants, children and young people up to the age of 18 years (refer to the SEL Paediatric Formulary for dose guidance in neonates)**

*This document is for guidance only and not intended to replace the health professionals' clinical judgement for individual patients. The South East London Integrated Medicines Committee has separate guidance for management of vitamin D deficiency in adults including CKD and pregnancy and lactation.*

### **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<sup>[1]</sup>. The term 'vitamin D' generally refers to two very similar molecules. Vitamin D<sub>3</sub>, also known as colecalciferol, is the most abundant in humans and is produced in the skin following exposure to sunlight<sup>[1]</sup>. Vitamin D<sub>2</sub>, or ergocalciferol, occurs naturally in some mushrooms and yeast. The amount in most other vegetables is negligible.

The body converts both forms of vitamin D to 25-hydroxyvitamin D (25OHD). Tests to assess vitamin D status measure levels of 25OHD in the blood.

The main manifestation of vitamin D deficiency is rickets in children. Based on the overall evidence, it is not possible to discern a clear threshold serum 25OHD concentration below which rickets occurs. However, rickets with unknown aetiology, often with serum 25OHD concentration <30 nmol/L, is usually defined as vitamin D deficiency rickets<sup>[1]</sup>.

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 recommendations of the South East London Paediatric Formulary (SEL Paediatric Formulary), [Royal College of Paediatricians and Child Health \(RCPC\) Guide for vitamin D in infants, children and young people 2018](#)<sup>[2]</sup>, the [Royal Osteoporosis Society \(ROS\) Vitamin D and Bone: A Practical Clinical Guideline for Patient Management in Children and Young People 2018](#)<sup>[3]</sup> and the [Global Consensus Recommendations on the Prevention and Management of Nutritional Rickets 2016](#)<sup>[4]</sup>. It sets out to provide guidance on:

- Management of low vitamin D levels in infants, children and young people (flowchart)
- Signs and symptoms of vitamin D deficiency in infants, children and young people
- Licensed vitamin D products to treat deficiency in infants, children and young people
- General information and advice on the prevention and management of vitamin D deficiency
- Use of intramuscular ergocalciferol, STOSS therapy and PIMS-TS (secondary care only)
- Vitamin D overdose and toxicity

**Before using this guidance, refer to a specialist for advice if an infant, child or young person:**

- Has clinical features of rickets
- Has repeated hypocalcaemia
- Has raised parathyroid hormone levels - primary hyperparathyroidism (hypercalcaemia)

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- Has a fragility fracture, documented osteoporosis, high fracture risk, or is being treated with an antiresorptive drug for bone disease
- Is pregnant
- Has a malabsorption disorder (for example Crohn's disease, Cystic Fibrosis)
- Has a history of sarcoidosis, renal stones, tuberculosis, or lymphoma
- Has a diagnosis of stage 3b CKD (or greater)

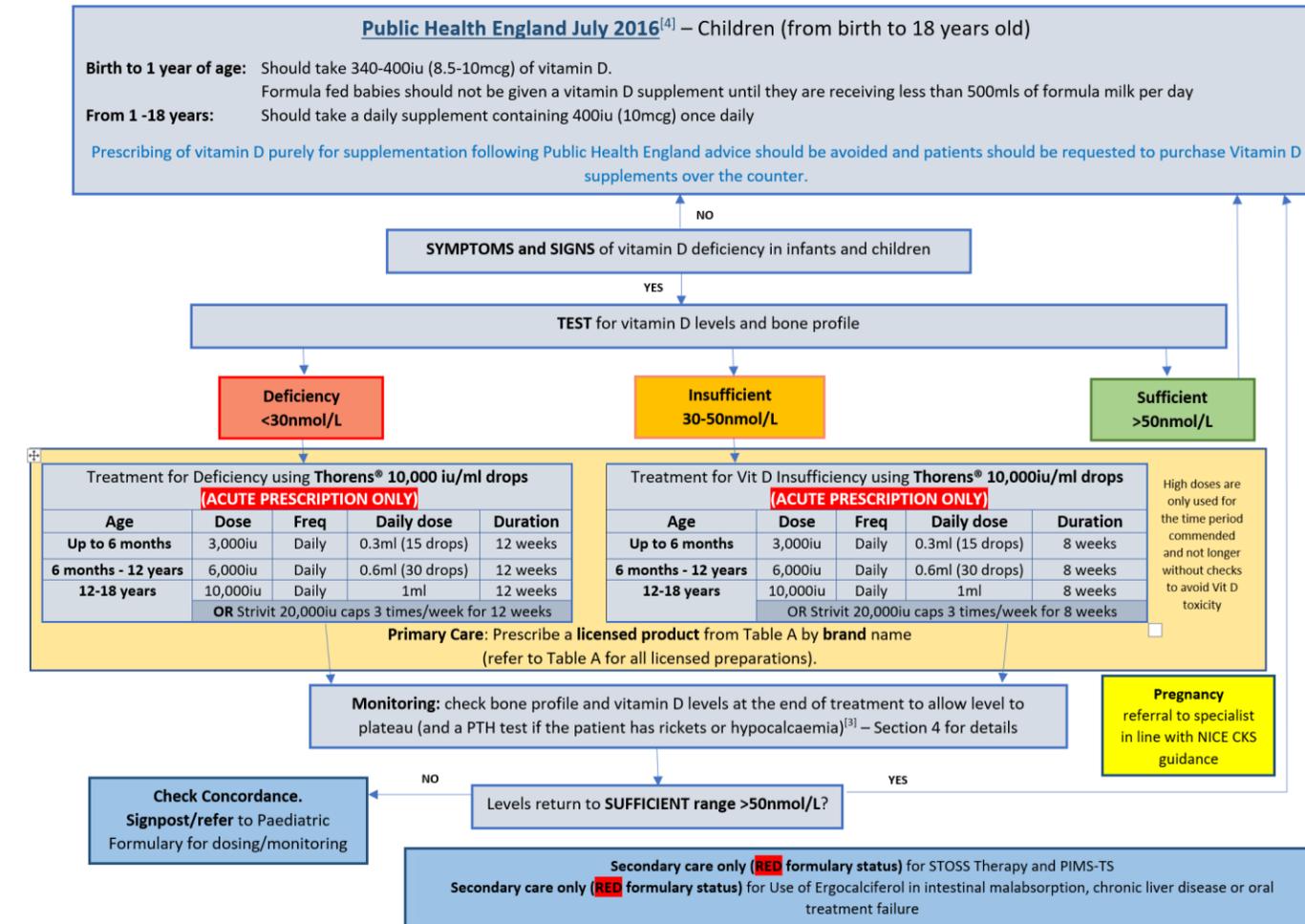
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## Flow Chart for management of low vitamin D levels in infants, children and young people

Public Health England advise that during the autumn and winter months **EVERYONE**, including children and young people, should consider taking a daily supplement containing at least 10 micrograms (400 international units (IU)) of vitamin D, which can be purchased over the counter (see section 5). Children and young people at high risk of vitamin D deficiency (see section 3) should consider a daily vitamin D supplement throughout the year. If a clinician is unsure about how to manage vitamin D deficiency they should seek advice and guidance from a specialist prior to referral and/or recommending or prescribing supplementation.



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### 3. Signs and symptoms of vitamin D deficiency in infants, children and young people

Infants	Seizures, tetany and cardiomyopathy (features of hypocalcaemia)
Children	Aches and pains (unexplained); myopathy causing delayed walking; rickets with bowed legs, knock knees, poor growth and muscle weakness e.g. difficulty climbing stairs, waddling gait, difficulty rising from a chair.
Adolescents	Aches and pains, muscle weakness, bone changes of rickets or osteomalacia, tetany, seizures, acute respiratory tract infections

Note that signs and symptoms of vitamin D deficiency may be non-specific, and therefore risk factors for vitamin D deficiency must also be considered. These include <sup>[3]</sup>:

- Diets insufficient in calcium (e.g. vegan, low dairy intake, dairy exclusion) or poor general diet.
- Limited sun exposure (e.g. veiled and photosensitive patients, those advised to apply high factor sun block due to malignancy risk).
- Little time spend outdoors (e.g. children and young people with limited mobility).
- Infants, children and young people with dark skin, for example people of African, AfricanCaribbean or South Asian origin.
- Infants, children and young people taking anticonvulsants that induce liver enzymes (e.g. phenytoin, carbamazepine, phenobarbital).
- Infants, children and young people who have family members with proven vitamin D deficiency.

### 4. Licensed vitamin D products to treat vitamin D deficiency in infants, children and young people

**Table A:** licensed colecalciferol products available for treating vitamin D deficiency, as recommended by the SEL Paediatric Formulary. Prescribers are advised to refer to the SEL Paediatric Formulary for dosage and monitoring information. Prescribing by brand is recommended.

Table A: Licensed colecalciferol products available on FP10 as recommended by the SEL Paediatric Formulary				
Dosage / quantity required to meet dosing recommendations of SEL Paediatric Formulary will differ from those recommended by currently licensed preparations (off – label dosing)				
Product	Suitable in soy or peanut allergy?	Suitable for vegetarians	Suitable for Halal/Kosher	Additional Information
<b>Thorens®</b> 10,000 units/ml oral drops (10ml bottle) Legal category: POM	Yes	Yes	Yes	Licensed in UK from birth. Gluten free & lactose-free. Should be preferably taken with a meal. Can be mixed with small amount of food such as yogurt, milk or other dairy products but entire dose must be taken. Shelf life 6 months after opening. <b>1 drop is equivalent to 200 units</b>
<b>Strivit D3 20,000unit capsules</b> Legal category: POM	Yes	No (gelatine capsule)	Yes	<b>First Line if a solid dosage form is preferred for patients aged 12-18 years</b>  Treatment dose: 20,000IU three times per week for 12 weeks  Licensed in UK for children and young people aged 12-18 years Lactose free

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<b>Colextra D3 20,000unit capsules</b> Legal category: POM	Yes	No (gelatine capsule)	Unknown	Treatment dose: 20,000IU three times per week for 12 weeks Licensed in UK for children and young people aged 12-18 years
<b>Invita D3 25,000unit capsules</b> Legal category: POM	Yes	No (gelatine capsule)	Yes	Treatment dose for <b>12yo+</b> : 25,000IU three times per week for 11 weeks Licensed in UK for children and young people aged 10-18 years
<b>Stexerol D3 25,000units tablets</b> Legal category: POM	Yes	Yes	Yes	<b>Second Line if a solid dosage form is preferred for patients aged 12-18 years AND patient is vegetarian</b> Treatment dose: 25,000IU three times per week for 11 weeks Licensed in UK for children and young people aged 12-18 years
<b>Colextra D3 25,000unit tablets</b> Legal category: POM	Yes	Yes	Yes	Treatment dose: 25,000IU three times per week for 11 weeks Licensed in UK for children and young people aged 12-18 years
<b>Fultium D3 20,000 units capsules</b>	No	No (gelatine capsule)	Yes	Treatment dose: 20,000IU three times per week for 12 weeks Licensed in UK for children and young people aged 12-18 years

### Prescribing Consideration:

- Prescribe a **licensed product** from Table A by **brand** name to ensure:
  - **Patient safety** - Generic prescribing of colecalciferol or those marketed as food supplements may potentially result in a product being supplied that has significant deviations from labelled concentrations, leading to dosing errors, including the risk of overdose [Food Standards Agency](#) <sup>[13]</sup>. Therefore, it is recommended that licensed products are only prescribed and dispensed by brand for the management of low vitamin D levels in infants, children and young people.
  - Patient-specific needs are considered e.g. suitability for [vegetarians or vegans](#) <sup>[14]</sup>.
- Colecalciferol is derived from lanolin (sheep's wool fat). It would remain the patient's (or parent's/carer's) decision as to whether the ingredients are acceptable. Oral ergocalciferol may be considered as an alternative for those individuals with strict dietary beliefs – please refer to the borough medicines management team for advice.

**Monitoring:** check bone profile and vitamin D levels at the end of treatment to allow level to plateau (and a PTH test if the patient has rickets or hypocalcaemia)<sup>[3]</sup>. If treatment is initiated in secondary care, the discharge summary to the GP must include the following details:

- Date treatment course started
- Date treatment course will complete
- Communication to GP to repeat bone profile and vitamin D level after treatment course completed (if plan to repeat levels in secondary care, the discharge summary must state this).

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## 5. General information and advice

### Natural ways of increasing Vitamin D levels

#### i. 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 21<sup>st</sup> 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. Children from ethnic minority groups with dark skin, from African, Afro-Caribbean and South Asian backgrounds, 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<sup>5</sup>.

***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.

#### ii. Dietary advice and Healthy Start Vitamin Scheme

Adequate vitamin D intake may be difficult to achieve with diet alone and parents may choose to supplement by purchasing vitamin D products. Please see the SEL [vitamin D patient leaflet](#) for sources of dietary vitamin D, as well as [NHSE OTC guidance](#) and local self-care position statement for further information.

Children from birth to their fourth birthday who are eligible beneficiaries can access free Healthy Start vitamins vouchers under the government Healthy Start scheme. Refer parents to the Healthy Start website for further details <https://www.healthystart.nhs.uk> or contact their local Midwife or Health Visitor. Some Clinical Commissioning Groups may supply Healthy Start vitamins freely to all children under four years old. Therefore, please refer to local vitamin D supply arrangements.

Free Healthy Start vitamins should be recommended for eligible groups, in preference to issuing Dalivit<sup>®</sup> Drops or Abidec<sup>®</sup> Multivitamin Drops on FP10 prescriptions. For children who are not eligible for the Healthy Start scheme, supplements may be purchased over the counter. Note that studies have indicated that the actual vitamin D content of products marketed as nutritional supplements (i.e. those without a marketing authorisation) may be less than that claimed on the product packaging<sup>[9]</sup>. When purchasing vitamin D, patients and carers should check that the product contains the recommended dosage of 10micrograms (400 units) of vitamin D.

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**Table B:** licensed multivitamin products containing vitamin D that are available to purchase over the counter (OTC).

<b>Table B: Multivitamins containing Vitamin D for standard prevention doses available to buy over the counter - SELF-CARE</b>		
<small>(UK marketing authorisation holders only – all available as oral drops solutions) *No other formulation currently holds a MA</small>		
<b>Products</b>	<b>Suitable for Vegetarians</b>	<b>Additional Information</b>
Abidec® Multivitamin Drops for Babies and Toddlers containing ergocalciferol 400 units/0.6ml	No	Licensed for 1- 12 years: 0.6ml daily equivalent to 400 units ergocalciferol. Also contains: 1333 units retinol (as vitamin A palmitate), 0.4 mg thiamine hydrochloride, 0.8 mg riboflavin, 0.8 mg pyridoxine hydrochloride, 8 mg nicotinamide, and 40 mg ascorbic acid. Contains arachis oil; <b>avoid in those with peanut allergy.</b>
Dalivit® Oral Drops containing ergocalciferol 400 units/0.6ml	Yes	Licensed for 1 - 12 years: 0.6ml daily equivalent to 400 units ergocalciferol. Also contains: 5000 units vitamin A (as palmitate), 1 mg thiamine, 400 micrograms riboflavin, 500 micrograms pyridoxine hydrochloride, 5 mg nicotinamide, and 50 mg ascorbic acid. Does not contain peanut oil. Suitable if keen to avoid animal source.
Healthy Start Vitamin Drops for Children	Yes	Dose for 0 – 4 years old: 5 drops equivalent to 400 units colecalciferol. Also contains: 233 micrograms vitamin A, 20mg vitamin C Free from milk, egg, gluten, soya and peanut residues <sup>[8]</sup> <i>Healthy Start helpline on <a href="http://www.healthystart.nhs.uk">www.healthystart.nhs.uk</a> or ask local health visitor</i>

## 6. Use of intramuscular ergocalciferol for intestinal malabsorption, chronic liver disease or oral treatment failure

The SEL Paediatric Formulary recommends the use of ergocalciferol solution for injection 300,000 units in 1ml for treatment of vitamin D deficiency in intestinal malabsorption, chronic liver disease or previous oral treatment failure. Prescribing and monitoring of ergocalciferol as vitamin D supplementation will remain the responsibility of the specialist secondary care team.

## 7. Vitamin D Toxicity and symptoms of overdose

In statements released over the last decade, The UK Scientific Advisory Committee on Nutrition <sup>[1]</sup>, the Institute of Medicine (IOM) <sup>[7]</sup> and the US Endocrine Society <sup>[12]</sup> have concluded that acute vitamin D toxicity is extremely rare in the literature, that serum 25(OH)D concentrations must exceed 150 ng/ml (375 nmol/l), and that other factors, such as calcium intake, may affect the risk of developing hypercalcemia and vitamin D toxicity<sup>[13]</sup>.

In 2012, the European Food Safety Authority (EFSA) revised the Tolerable Upper Intake Levels (UL) (EFSA, 2012) for all age groups. A UL is intended to apply to all groups of the general population, including more sensitive individuals, but with the exception in some cases of discrete, identifiable subpopulations who may be especially vulnerable to one or more adverse effects (e.g., those with unusual genetic predisposition, certain diseases, or receiving the nutrient under medical supervision)<sup>[1]</sup>.

The Committee on toxicity of chemicals in food, consumer products and the environment (COT) agreed that the ULs for vitamin D set by EFSA, of 1000, 2000 and 4000 units/day for children aged 0-12 months, 1-10y and 11-17y respectively, were appropriate. There were insufficient data to specify a safe upper

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limit for single or occasional high doses in children, but the consensus agreed was that toxicity could occur from a dose of  $\geq 600,000$  units<sup>[1,8]</sup>.

The symptoms of vitamin D overdose can vary from mild to serious. Some, like nervousness and irritability, are emotional, but physical signs can present as nausea, vomiting, loss of appetite and accompanying weight loss. Individuals may also become dehydrated and experience increased thirst and severe headaches. As symptoms progress, the nerves and muscles are affected, leading to itchy skin, fatigue and weakness. More serious issues of vitamin D toxicity in the body lead to elevated levels of calcium in the blood and soft tissues (like the lungs, heart and kidneys). At this point, bone pain or bone loss can occur. Individuals will also exhibit urinary tract symptoms ranging from excessive production of urine to kidney stones or renal failure. High blood pressure and an increased risk of heart disease are concerns and ultimately can lead to irrevocable damage to major organs.

In any suspected case of vitamin D toxicity the supplement should be stopped and advice from a paediatric endocrine and/or metabolic specialist should be sought.

## 8. STOSS Therapy and PIMS-TS

Single high-dose oral vitamin D3 therapy (STOSS) and treatment for Paediatric Multisystem Inflammatory Syndrome (PIMS-TS) must only be initiated in secondary care. There is a lack of evidence for vitamin D treatment in PIMS-TS; the rationale for prescribing is that children with a

diagnosis of PIMS-TS were observed to have low vitamin D levels. Prescribing information for these indications may be found in the SEL Paediatric Formulary.

## 9. Additional Information for all prescribers

Viapath Pathology Laboratories used by GSTT (Guy's and St Thomas' NHS Foundation Trust) and KCH (Kings College Hospital), as well as Lewisham and Greenwich Laboratories define 30 nmol/L as their deficiency cut-off for vitamin D in adults and children. This differs from the RCPCH deficiency cut-off at 25nmol/L for vitamin D in children. Viapath have given their assurance, that their cut-off ensures that no child with a value of  $< 25$  nmol/L for 25OHD would be mis-diagnosed as having normal D status.

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