Public Health England Update July 2016


The advice notes that vitamin D is made in the skin on exposure to UVB in sunlight, but since this is difficult to quantify, a daily dietary intake of 10 micrograms equivalent to 400 international units (IU) is being recommended.

It is noted that in spring and summer the majority of the population get enough vitamin D through sunlight on the skin and a healthy, balanced diet. In autumn and winter months it is difficult for people to meet the 10 microgram recommendation from consuming foods naturally containing or fortified with vitamin D, so people should consider taking a daily supplement containing 10 micrograms (400 IU).

The advice also considers people whose skin has little or no exposure to the sun, like those in institutions such as care homes, or who always cover their skin when outside, and recommends that they need to take a supplement throughout the year.

**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**.

Recommendations are also made for children under 5.

**Birth up to one year of age:**
- Exclusively or partially breastfed babies should be given a daily supplement containing 8.5-10 micrograms (340-400 IU) vitamin D
- Formula fed babies should not be given a vitamin D supplement until they’re receiving less than 500ml of formula milk a day

**Children aged 1 – 4 years:**
- Should be given a daily supplement containing 10 micrograms (400 IU) vitamin D

**Aged 5 years and above:**
- Between late March/early April and September - the majority of people aged 5 years and above will probably obtain sufficient vitamin D from sunlight when they are outdoors, alongside foods that naturally contain or are fortified with vitamin D. As such, they might choose not to take a vitamin D supplement during these months.
- From October to March – **EVERYONE**, including pregnant and breastfeeding women, should consider taking a daily supplement containing 10 micrograms (400 IU) of vitamin D.

It is noted that low-income families can access vitamin D free of charge via Healthy Start schemes.

**Action:** Clinicians should be aware of this new advice. The advice consistently refers to "dietary sources" of vitamin D including foods naturally containing or fortified with vitamin D and supplements.

**Prescribing of vitamin D purely for supplementation following this advice is not recommended.**
Flow Chart 1: Management of Low Vitamin D Levels in Adults over 18 years old

Routine testing of 25-hydroxyvitamin D (25-OHD) level is not recommended

Patient with high risk factors that may increase risk of vitamin D deficiency (Table A) or patient at higher risk of having a low vitamin D status or “at-risk group” (Table B)

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

- Symptoms of rickets include: tetany, leg bowing or knock knees, anterior bowing of femur, painful wrist swelling, softening of the skull, spinal curvature, bone pain.
- Symptoms of osteomalacia include: bone pain or tenderness, proximal muscle weakness.

**Box 1:** Colecalciferol 800 - 2000 units daily
Patients given lifestyle advice and advised to buy Vitamin D supplements over the counter available in strengths, **800 units - 2000 units daily. No routine monitoring required.**

NICE and NOS recommends additional daily supplementation of 1000mg calcium e.g. **Evacal-D3® chewable tablet** if low intake of dairy products and fish for osteoporosis/prevention of fragility fractures.

**YES**

**TEST** for vitamin D levels and bone profile

- **Deficient: 25-OHD < 30nmol/L**
  - **Treatment dose**
    - Prescribe as acute items. Do not put on repeat.
    - Oral capsules: 40,000 units colecalciferol **weekly** for 7 weeks (**Plenachol® 40,000 unit capsules**)
    - Patients with swallowing difficulties
    - Oral solution/drop: 50,000 units colecalciferol **weekly** for 6 weeks (**Invita D3® 50,000units/ml oral solution**)
    - If patient cannot tolerate oral preparation/severe gastro malabsoprtion
    - IM injection: 300,000 units or 600,000 units ergocalciferol once or twice only

- **Insufficient: 25-OHD = 30-50nmol/L**
- **Sufficient: 25-OHD > 50nmol/L**

**NO**

**Monitoring:** check serum calcium levels 4 weeks after starting treatment.

**Following treatment dose, provide lifestyle advice and advise to buy vitamin D supplements over the counter (refer to box 1)**

For patients under the care of the renal team please seek specialist advice regarding management.
### Table A: Patient with high risk factors that may increase risk of vitamin D deficiency

<table>
<thead>
<tr>
<th>Patients with a significant risk of osteoporosis e.g.</th>
</tr>
</thead>
<tbody>
<tr>
<td>- High corticosteroid use e.g. inflammatory bowel disease, rheumatoid arthritis, COPD</td>
</tr>
<tr>
<td>- Hypoparathyroidism</td>
</tr>
<tr>
<td>- Active cancer</td>
</tr>
<tr>
<td>- Sickle cell disease</td>
</tr>
<tr>
<td>- Prolonged immobilisation</td>
</tr>
<tr>
<td>- Liver disease</td>
</tr>
<tr>
<td>- Anorexia nervosa</td>
</tr>
<tr>
<td>- Vegan diet</td>
</tr>
</tbody>
</table>

- Patients with malabsorption states e.g. 
  - Small bowel resection 
  - Coeliac disease 
  - Bariatric surgery

- Fragility fracture despite osteoporosis drug treatment
- Fragility fracture at young age (<60 years)
- Patients on parenteral potent anti-resorptive agent (IV Bisphosphonate/Teriparatide/Denosumab)
- Pregnancy or breast feeding where severe deficiency is suspected
- Musculoskeletal symptoms that may be attributed to vitamin D deficiency e.g. Symptoms of osteomalacia

### Table B: Patient at higher risk of having a low vitamin D status or “at-risk group” (NICE PH56 Nov 2014)

<table>
<thead>
<tr>
<th>Testing for Vitamin D deficiency NOT recommended but require a pragmatic approach based on presumptive diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Black or South Asian patients or those with darker skin</td>
</tr>
<tr>
<td>Patients taking antiepileptics, antiretrovirals or aromatase inhibitors (these can impair vitamin D metabolism)</td>
</tr>
<tr>
<td>Patients with mental health issues including patients with epilepsy, schizophrenia and bipolar disorder being treated with anti-epileptic drugs.</td>
</tr>
<tr>
<td>Patients who have a sun sensitive condition, low or no exposure to the sun, for example, those who cover their skin for cultural reasons</td>
</tr>
<tr>
<td>Housebound patients and patients in institutionalised settings e.g. care homes, learning disability homes (calcium intake should also be considered)</td>
</tr>
<tr>
<td>Patients who have a high risk of falling/have fallen frequently</td>
</tr>
<tr>
<td>Elderly &gt;75 years</td>
</tr>
<tr>
<td>Obesity (BMI &gt; 30kg/m²)</td>
</tr>
<tr>
<td>Menopause</td>
</tr>
</tbody>
</table>

*If Alkaline Phosphatase (ALP) is noted as being raised in any patient in the above groups this may indicate more severe osteomalacia, in which case check 25OHD level.*

- Infants and children aged under 5-please refer to flow chart 2 for management in children
- Pregnant and breastfeeding women-please refer to flow chart 3 for management in pregnancy and breastfeeding women
Serum 25-hydroxyvitamin D (25-OHD)

<table>
<thead>
<tr>
<th>25-OHD &gt; 50nmol/L or &gt; 20microgram/L</th>
<th>Sufficient</th>
<th>RCPCH Standard Prevention dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>25-OHD 30-50nmol/L or 12-20microgram/L</td>
<td>Insufficient</td>
<td>RCPCH Standard Prevention dose</td>
</tr>
<tr>
<td>&lt; 30nmol/L or &lt;12microgram/L</td>
<td>Deficient</td>
<td>RCPCH Treatment dose</td>
</tr>
</tbody>
</table>

Children (from birth to 18 years old)

See page 1 for new PHE advice

Symptoms and signs of vitamin D deficiency in infants and children

Test for vitamin D levels and bone profile

Deficiency < 30nmol/L

Insufficient 30-50nmol/L

Sufficient > 50nmol/L

NO

No treatment required
Lifestyle advice including dietary advice. Advise to buy a vitamin D supplement OTC counter or referral to local vitamin D supply arrangements if applicable.

RCPCH Prevention Dose

<table>
<thead>
<tr>
<th>Age</th>
<th>Dosage and frequency</th>
<th>CCG recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Newborn up to 1 month</td>
<td>300 – 400 units daily</td>
<td>OTC preparations or Healthy Start Children’s vitamin drops</td>
</tr>
<tr>
<td>1 month - 18 years</td>
<td>400 – 1,000 units daily</td>
<td>OTC preparations or Healthy Start Children’s vitamin drops</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Age</th>
<th>Treatment dose, duration and product recommendations</th>
</tr>
</thead>
</table>
| 0 to 18 years | Thorens® 10,000 units/ml oral drops: 2,000 units (10 drops) daily for 6 weeks  
Thorens® 25,000 units/2.5ml: 25,000 units (1 bottle) once every 2 weeks for 6 weeks  
Plenachol® 20,000 unit capsules: 20,000 units (1 capsule) once every 2 weeks for 6 weeks  
(Plenachol® 20,000 unit capsules licensed from 12-18 years) |

These products are licensed for the treatment of deficiency in children. The recommended dosage schedules are based on information contained in the product datasheets (SPC). The licensed doses may vary from the RCPCH treatment doses.

Monitoring: check serum calcium levels 4 weeks after starting treatment, and check vitamin D levels at 12 weeks to allow level to plateau

Levels return to SUFFICIENT range?

Check adherence, refer to paediatric specialist for advice/referral

YES

Lifestyle advice including dietary advice. Advise to buy a vitamin D supplement OTC counter or referral to local vitamin D supply arrangements. Refer to RCPCH prevention dose

Deficiency < 30nmol/L

Insufficient 30-50nmol/L

Sufficient > 50nmol/L

Stoss regime: For use by secondary care in children with malabsorption symptoms, high risk of rickets and vitamin D < 15nmol/L. Ergocalciferol by IM injection up to 300,000 units as a single dose (dose dependent on age), as directed by the paediatrician.

Approved: Medicines Management Committee, January 2017
Review date: January 2019
**Flow Chart 3: Management of Low Vitamin D Levels in Pregnancy or Breastfeeding Women**

**Pregnant and Breastfeeding Women**
DoH guidance recommends 400 units (10 mcg) colecalciferol daily from OTC products or Healthy Start Women’s Vitamins tablets. **Do not prescribe maintenance supplementation.**

- **TEST** for vitamin D levels and bone profile only if patients have SYMPTOMs indicative of rickets, osteomalacia or symptomatic hypocalcaemia?
  - **Severe deficiency** < 15nmol/L → Urgent advice or referral to an obstetrician for consideration of rapid correction dose
  - **Deficiency** 15-29nmol/L → Correction dose: for 2nd or 3rd trimester *Fultium-D3*® 3,200 unit capsules daily for 12 weeks is the only licensed product to provide a cumulative dose of around 150,000 or 300,000 units per treatment course (4000 units daily is recommended by UKMi and RCOG). Seek advice from obstetrician for women in 1st trimester.
  - **Insufficiency** 30-50nmol/L → **Sufficient** > 50nmol/L → Continue on DoH recommendation of 400 units daily
  - **Levels ≥ 30nmol/L** → YES
  - **Check adherence, specialist advice/referral** → **NO**

**Monitoring:** check serum calcium levels 1 month and 4 months after starting treatment. Check vitamin D levels 3 months after starting treatment to allow levels to plateau.

**References:**
1. **NICE guideline PH56: Vitamin D: increasing supplement use in at-risk groups.** November 2014
2. **National Osteoporosis Society (NOS) – Vitamin D and Bone Health: A Practical Clinical Guideline for Patient Management.** April 2013
3. **Royal College of Paediatrics and Child Health (RCPCH) Guide to Vitamin D in Childhood.** October 2013
4. **UKMi Which oral vitamin D dosing regimens correct deficiency in pregnancy.** June 2016
5. **Fultium-D3® 3,200 unit SPC** https://www.medicines.org.uk/emc/medicine/28806
6. **Royal College of Obstetricians and Gynaecologists (RCOG) Vitamin D in Pregnancy.** June 2014
7. **SACN vitamin D and health report - Publications - GOV.UK** July 2016

**Acknowledgements:**
Adopted and adapted with permission from Greenwich CCG Medicines Management Team
## Appendix 1: Licensed vitamin D Products and allergy information

<table>
<thead>
<tr>
<th>Product</th>
<th>Suitable in soy or peanut allergy?</th>
<th>Suitable for vegetarians?</th>
<th>Kosher and Halal considerations</th>
<th>Additional Information</th>
<th>Pack Size</th>
<th>Cost (Jan 2017)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Desunin® tabs 800 units</td>
<td>Yes</td>
<td>Yes</td>
<td>Contains no gelatin or porcine sourced excipients</td>
<td>Licensed in UK for doses 1-5 tablets daily. Tablets can be swallowed whole or crushed or taken with food.</td>
<td>30</td>
<td>£3.60</td>
</tr>
<tr>
<td>Fultium-D3® caps 800 units</td>
<td>Yes</td>
<td>No</td>
<td>Gelatin is of bovine origin, no porcine sourced excipients</td>
<td>Lactose free Contains maize oil</td>
<td>90</td>
<td>£8.85</td>
</tr>
<tr>
<td>Fultium-D3® caps 3,200 units</td>
<td>Yes</td>
<td>No</td>
<td>Gelatin is of bovine origin, no porcine sourced excipients</td>
<td>Lactose free Contains maize oil Only licensed product in pregnancy &amp; breast feeding</td>
<td>30</td>
<td>£13.32</td>
</tr>
<tr>
<td>Fultium-D3® caps 20,000 units</td>
<td>Yes</td>
<td>No</td>
<td>Gelatin is of bovine origin, no porcine sourced excipients</td>
<td>Lactose free Contains maize oil</td>
<td>30</td>
<td>£29.00</td>
</tr>
<tr>
<td>Invita D3® oral dropper solution 2,400 units/ml</td>
<td>Yes</td>
<td>Yes</td>
<td>Contains no gelatin or porcine sourced excipients</td>
<td>1ml solution (36 drops) equivalent to 2,400 units</td>
<td>10ml (360 drops)</td>
<td>£3.60</td>
</tr>
<tr>
<td>Invita D3® oral solution 25,000 units/ml</td>
<td>Yes</td>
<td>Yes</td>
<td>Contains no gelatin or porcine sourced excipients</td>
<td>Plastic 1 ml ampoule with twist top</td>
<td>3 amps</td>
<td>£4.45</td>
</tr>
<tr>
<td>Invita D3® oral solution 50,000 units/ml</td>
<td>Yes</td>
<td>Yes</td>
<td>Contains no gelatin or porcine sourced excipients</td>
<td>Plastic 1 ml ampoule with twist top</td>
<td>3 amps</td>
<td>£6.25</td>
</tr>
<tr>
<td>Plenachol® caps 20,000 units</td>
<td>Yes</td>
<td>Yes</td>
<td>Contains no gelatin or porcine sourced excipients</td>
<td>Lactose free</td>
<td>10</td>
<td>£8.33</td>
</tr>
<tr>
<td>Plenachol® caps 40,000 units</td>
<td>Yes</td>
<td>Yes</td>
<td>Contains no gelatin or porcine sourced excipients</td>
<td>Lactose free</td>
<td>10</td>
<td>£15.00</td>
</tr>
<tr>
<td>Thorens® oral solution 25,000 units/2.5ml</td>
<td>Yes</td>
<td>Yes</td>
<td>Halal and kosher certified</td>
<td>Lactose free</td>
<td>2.5ml</td>
<td>£1.55</td>
</tr>
<tr>
<td>Thorens® oral drops 10,000 units/ml</td>
<td>Yes</td>
<td>Yes</td>
<td>Halal and kosher certified</td>
<td>Lactose free 1 drop equivalent to 200 units</td>
<td>10ml (500 drops)</td>
<td>£5.85</td>
</tr>
<tr>
<td>Healthy Start Vitamin Drops for Children</td>
<td>Yes</td>
<td>Yes</td>
<td>Halal and kosher certified</td>
<td>5 drops equivalent to 300 units</td>
<td>10ml</td>
<td>Healthy Start helpline on 0845 607 6823 <a href="http://www.healthystart.nhs.uk">www.healthystart.nhs.uk</a></td>
</tr>
</tbody>
</table>