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TREATMENT OF VITAMIN D DEFICIENCY IN AT-RISK ADULTS (SECOND EDITION)

Executive Summary

Vitamin D deficiency is normally defined as a concentration of 25 hydroxyvitamin D of less than 25nmol/litre. This is the level below which parathyroid hormone (PTH) starts to rise causing increased bone turnover and hence the symptoms associated with osteomalacia (these include rickets in children and osteoporosis and fractures in adults). Vitamin D is seasonal, but replete levels should be > 75 nmol/L. The table below identifies different levels of deficiency according to 25 hydroxyvitamin D levels and recommends a range of different approaches to treatment dependent upon the level of deficiency.

Level of deficiency	25 hydroxyvitamin D level	Recommended treatment
Severe deficiency (associated with osteomalacia including rickets in children and osteoporosis and fractures in adults)	<25 nmol/l 25 hydroxyvitamin D	<u>Capsule formulations:</u> Dose: 40,000 IU weekly for 7 weeks. Preferred products: <i>Aviticol</i> 20,000IU capsules <i>Fultium D3</i> 20,000IU capsules <i>Plenachol</i> 20,000IU and 40,000IU capsules <u>Liquid formulations</u> Dose: 50,000IU weekly for 6 to 8 weeks. Preferred products: <i>InVita D3</i> oral solution 25,000IU in 1ml <i>Thorens</i> oral solution 25,000IU in 2.5ml
Deficiency associated with disease risk	25-50 nmol/l 25 hydroxyvitamin D	If symptoms are severe, treat with preferred products and licensed doses detailed above. If physical symptoms are milder, lower doses are indicated Dose: 800-1600 IU daily for 12 weeks. Preferred products: <i>Desunin</i> 800IU tablets <i>Fultium D3</i> 800IU capsules
Insufficiency	50-75nmol/l 25 hydroxyvitamin D	If physical symptoms are present, prescribe 800-1600 IU daily for 12 weeks (as detailed above). If patient has no physical

		symptoms, consider lifestyle advice including: increased dietary intake and safe sun exposure (see <i>PACE Bulletin</i> Vol 6 No 6 Prevention of vitamin D deficiency in at-risk groups (May 2012)).
Replete	>75nmol/l 25 hydroxyvitamin D	No treatment necessary

Note: The immunoassay used in the Path Links laboratories does not detect D2 (ergocalciferol) or D3 (colecalciferol), instead it measures the 25 hydroxylated metabolite.

- **All of the preferred first-line products named in the table are designated GREEN and are approved for use through the *Lincolnshire Joint Formulary*.**
- **In order to prevent confusion with similar strength unlicensed food supplements, all colecalciferol products should be prescribed by preferred brand name. Prescribers are asked to review existing patients receiving vitamin D supplementation to ensure that preferred products prescribed by brand are being prescribed wherever possible.**
- **Unlicensed vitamin D formulations classed as either unlicensed specials or food supplements should only be used as a last resort when the patient's clinical needs cannot be met using a licensed product. Further information on available products is provided in Appendix 1.**
- **Where an injectable formulation of vitamin D is required, ergocalciferol injection 300,000IU/ml (Focus Pharmaceuticals) holds a UK marketing authorisation and is preferred.**

Maintenance treatment

Maintenance therapy is indicated for:

- **Those diagnosed with and treated for severe deficiency (i.e. those with pre-treatment levels of 25 hydroxyvitamin D of <25nmol/l and those with pre-treatment levels of 25 hydroxyvitamin D of between 25-50nmol presenting with severe symptoms and treated with the higher doses of colecalciferol).**
- **Those with pre-treatment levels of 25-50 nmol/l 25 hydroxyvitamin D or 50-75nmol/l 25 hydroxyvitamin D once deficiency has been corrected, if they are still considered at risk (e.g. housebound patients).**
- **Preferred products with licensed maintenance doses are tabulated below. Maintenance doses vary according to the products used:**

Product	Maintenance dose
Colecalciferol (<i>Aviticol</i>) 20,000IU capsules (Colonis Pharma)	2—3 capsules per month (1400-2000IU/day)
Colecalciferol (<i>Fultium D3</i>) 20,000IU capsules (Internis)	2—3 capsules per month (1400-2000IU/day)
Colecalciferol (<i>Plenachol</i>) 20,000IU capsules	2—3 caps per month (1400-2000) IU/day
Colecalciferol (<i>Desunin</i>) 800IU tablets (Meda)	1-2 tablets daily (800-1600IU/day)
Colecalciferol (<i>Fultium D3</i>) 800IU capsules (Internis)	1-2 capsules daily (800-1600IU/day)
Colecalciferol (<i>InVita D3</i>) oral solution 25,000IU in 1ml (Consilient Health)	25,000IU per month (1ml)

Colecalciferol (<i>Thorens</i>) oral solution 25,000IU in 2.5ml	25,000IU per month (2.5ml)
Product	Maintenance dose
<i>Aviticol</i> 20,000IU capsules (Colonis Pharma)	2—3 capsules per month (1400-2000IU/day)
<i>Fultium D3</i> 20,000IU capsules (Internis)	2—3 capsules per month (1400-2000IU/day)
<i>Plenachol</i> 20,000IU capsules	2—3 caps per month (1400-2000) IU/day
<i>Desunin</i> 800IU tablet (Meda)	1-2 tablets daily (800-1600IU/day)
<i>Fultium D3</i> 800IU capsules (Internis)	1-2 capsules daily (800-1600IU/day)
<i>InVita D3</i> oral solution 25,000IU in 1ml (Consilient Health)	25,000IU per month (1 ml)
<i>Thorens</i> oral solution 25,000IU in 2.5ml	25,000IU per month (2.5ml)

- **Patients who have been successfully treated for vitamin D deficiency for whom prescribed maintenance therapy is not indicated, should be encouraged to make lifestyle changes such as increasing dietary intake of vitamin D, increasing safe sun exposure and increasing vitamin D intake with supplements purchased from community pharmacies, health food stores or other reputable retailers (see *PACE Bulletin* Vol 6 No 6 Prevention of vitamin D deficiency in at-risk groups (May 2012)).**

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TREATMENT OF VITAMIN D DEFICIENCY IN AT-RISK ADULTS (SECOND EDITION)

Introduction

Around 20% of adults in the UK have low levels of vitamin D. As the main natural source of vitamin D is through the action of sunlight on the skin, the percentage of adults between 19 and 64 with low vitamin D levels escalates from 8% in the summer to 39% in the winter. In adults with darker skin, vitamin D deficiency is even more common with 75% of adults having low vitamin D levels in the winter. Within this context, NICE have striven to raise the profile of vitamin D deficiency both with healthcare professionals and with the public.

PACEF do not recommend the prescribing of vitamin D supplements for the *prevention* of vitamin D deficiency in those at risk. However, lifestyle advice and advice on access to *Healthy Start* vitamins and appropriate supplements to buy over the counter is provided in *PACE Bulletin* Vol 6 No 6 *Prevention of vitamin D deficiency in at-risk groups* (May 2012)).

This *Bulletin* provides updated guidance on the *treatment* of proven vitamin D deficiency in adults.

Screening for vitamin D deficiency

Population screening by measuring vitamin D levels is unnecessary, even in high risk populations. Investigations to determine the presence of vitamin D deficiency should only be

carried out if the patient presents with one or more of the symptoms of vitamin D deficiency and falls within one or more of the at risk categories listed below.

<u>Symptoms suggestive of vitamin D deficiency in adults</u>	General vague aches and pains (most commonly)
	Severe pain and also weakness that may lead to difficulty standing up or climbing stairs (more severe deficiency).
	Bone pains, typically felt in the ribs, hips, pelvis, thighs and feet.
	Proximal muscle weakness (i.e. in the quadriceps and glutei); may cause difficulty rising from a chair and /or a waddling gait.
	More diffuse muscular aches and muscle weakness, including in the limbs and back (may be labelled as “fibromyalgia” or as a somatisation of depression).
	Fractures typically femoral neck, scapula, pubic rami, ribs and vertebrae.
	Swelling, tenderness and redness at pseudo-fracture sites.
	Carpopedal spasm, tetany, seizures or irritability due to hypocalcaemia (requiring urgent treatment).

It is important to exclude other potential causes for the above symptoms such as myeloma, rheumatoid arthritis, polymyalgia and hypothyroidism. Patients presenting with a fracture will need to be assessed for the possibility of osteoporosis and treated in accordance with NICE and local guidance. While such patients would normally be started on an evidence based combination of calcium and vitamin D, an identified vitamin D deficiency based on 25-hydroxyvitamin D levels may necessitate the prescribing of a higher dose of vitamin D in accordance with doses recommended above.

Risk factors for vitamin D deficiency

Health care professionals need to ensure that those identified as being at risk get enough vitamin D either by increasing their exposure to sunlight, increasing dietary intake of vitamin D or through vitamin D supplementation..

<u>Risk factors for vitamin D deficiency</u>	All pregnant and breastfeeding women (especially teenagers and young women)
	Infants and young children under 5.
	Older people aged 65 and over.
	People who have low or no exposure to the sun (e.g. those who cover their skin for cultural reasons; the housebound or those confined indoors for long periods).
	People who have darker skin (e.g. people of African, African-Caribbean and South Asian origin) whose bodies cannot make as much vitamin D.
	People who suffer from medical conditions

	<p>that alter how the body handles vitamin D (e.g. pancreatic insufficiency, inflammatory bowel disease, Crohn's disease, coeliac disease, certain liver and kidney diseases, post bariatric surgery or post gastrectomy).</p> <hr/> <p>People taking certain medicines (e.g. carbamazepine, cholestyramine, glucocorticoids, orlistat, phenytoin, primidone, rifampicin, barbiturates, some anti-HIV medicines and transplant medicines).</p> <hr/> <p>People who are obese (vitamin D is sequestered in body fat).</p> <hr/> <p>People with severe liver failure, nephrotic syndrome or chronic kidney disease.</p>
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Biochemical investigations required to confirm vitamin D deficiency

The most reliable way to determine vitamin D deficiency is to assay the serum levels of 25-hydroxyvitamin D. If vitamin D deficiency is suspected, the following biochemical tests should be requested:

- 25 – hydroxyvitamin D
- Bone profile
- Parathyroid hormone (PTH) - to exclude primary hyperparathyroidism.
- Liver function tests (LFTs) - to exclude hepatic failure.
- Urea and electrolytes (U&E's) - to exclude renal failure.
- Full Blood Count (FBC) - anaemia may be present if there is malabsorption.

Specialist referral

Specialist referral will be necessary in patients with:

- Liver disease.
- Renal disease, including the presence of renal stones.
- Hypercalcaemia
- Metastatic cancer.
- Lymphoma.
- Sarcoidosis.
- Tuberculosis.
- Skeletal deformity.
- Short stature.
- Focal bone pain.
- Suspicion of malabsorption

Treatment of vitamin D deficiency

Colecalciferol (vitamin D3) is considered the preferred form of vitamin D for treatment as it raises vitamin D levels more effectively than ergocalciferol (vitamin D2) and has a longer duration of action. There are now five higher dose colecalciferol products (20,000IU- 25,000IU), and three lower strength products (800IU - 3200IU) which have UK product licenses for the treatment and prevention of vitamin D deficiency. Recommended products, doses and indications are tabulated below. These products should be used in preference to

food supplements or unlicensed specials which can be significantly higher in cost than licensed alternatives. **All prescribing should be by brand to ensure that lower cost licensed products are dispensed wherever possible.**

Level of deficiency	25 hydroxyvitamin D level	Recommended treatment
Severe deficiency (associated with osteomalacia including rickets in children and osteoporosis and fractures in adults)	<25 nmol/l 25 hydroxyvitamin D	<u>Capsule formulations:</u> Dose: 40,000 IU weekly for 7 weeks. Preferred products: <i>Aviticol</i> 20,000IU capsules <i>Fultium D3</i> 20,000IU capsules <i>Plenachol</i> 20,000IU and 40,000IU capsules <u>Liquid formulations</u> Dose: 50,000IU weekly for 6 to 8 weeks. Preferred products: <i>InVita D3</i> oral solution 25,000IU in 1ml <i>Thorens</i> oral solution 25,000IU in 2.5ml
Deficiency associated with disease risk	25-50 nmol/l 25 hydroxyvitamin D	If symptoms are severe, treat with preferred products and licensed doses detailed above. If physical symptoms are milder, lower doses are indicated Dose: 800-1600 IU daily for 12 weeks. Preferred products: <i>Desunin</i> 800IU tablets <i>Fultium D3</i> 800IU capsules
Insufficiency	50-75nmol/l 25 hydroxyvitamin D	If physical symptoms are present, prescribe 800-1600 IU daily for 12 weeks (as detailed above). If patient has no physical symptoms, consider lifestyle advice including: increased dietary intake and safe sun exposure (see <i>PACE Bulletin</i> Vol 6 No 6 Prevention of vitamin D deficiency in at-risk groups (May 2012)).
Replete	>75nmol/l 25 hydroxyvitamin D	No treatment necessary

Note: The immunoassay used in the Path Links laboratories does not detect D2 (ergocalciferol) or D3 (colecalciferol), instead it measures the 25 hydroxylated metabolite.

Unlicensed vitamin D containing tablets, capsules or liquid specials should only be prescribed for those patients who are unable to use the licensed products because of (1) intolerance to their excipients; (2) a vegetarian or vegan diet or (3) an atypical dosage regime (refer to Appendix 1 for further information).

Formulary Products

Drug	Indication(s)	Traffic Light and Joint Formulary Status
Colecalciferol (<i>Aviticol</i>) 20,000IU capsules (Colonis Pharma)	For the treatment of severe vitamin D deficiency (associated with osteomalacia including rickets in children and osteoporosis and	GREEN. Approved for use on the <i>Lincolnshire Joint Formulary</i> . First line preferred product. Dose: 40,000 IU weekly for 7 weeks.

	fractures in adults)	Prescribe by brand.
Colecalciferol (<i>Fultium D3</i>) 20,000IU capsules (Internis)	For the treatment of severe vitamin D deficiency (associated with osteomalacia including rickets in children and osteoporosis and fractures in adults)	GREEN. Approved for use on the <i>Lincolnshire Joint Formulary</i> . First line preferred product. Dose: 40,000 IU weekly for 7 weeks. Prescribe by brand.
Colecalciferol (<i>Plenachol</i>) 20,000IU and 40,000IU capsules	For the treatment of severe vitamin D deficiency (associated with osteomalacia including rickets in children and osteoporosis and fractures in adults)	GREEN. Approved for use on the <i>Lincolnshire Joint Formulary</i> . First line preferred product. Dose: 40,000 IU weekly for 7 weeks. Prescribe by brand.
Colecalciferol (<i>InVita D3</i>) oral solution 25,000IU in 1ml (Consilient Health)	For the treatment of severe vitamin D deficiency (associated with osteomalacia including rickets in children and osteoporosis and fractures in adults)	GREEN. Approved for use on the <i>Lincolnshire Joint Formulary</i> . Preferred liquid vitamin D preparation. Dose: 50,000IU weekly for 6 to 8 weeks. Prescribe by brand.
Colecalciferol (<i>Thorens</i>) oral solution 25,000IU in 2.5ml	For the treatment of severe vitamin D deficiency (associated with osteomalacia including rickets in children and osteoporosis and fractures in adults)	GREEN. Approved for use on the <i>Lincolnshire Joint Formulary</i> . Preferred liquid vitamin D preparation. Dose: 50,000IU weekly for 6 to 8 weeks. Prescribe by brand.
Colecalciferol (<i>Desunin</i>) 800IU tablets (Meda)	For the treatment of vitamin D deficiency associated with disease risk and insufficiency where physical symptoms are present.	GREEN. Approved for use on the <i>Lincolnshire Joint Formulary</i> . First line preferred product. Dose: 800-1600 IU daily for 12 weeks. Prescribe by brand.
Colecalciferol (<i>Fultium D3</i>) 800IU capsules (Internis)	For the treatment of vitamin D deficiency associated with disease risk and insufficiency where physical symptoms are present.	GREEN. Approved for use on the <i>Lincolnshire Joint Formulary</i> . First line preferred product. Dose: 800-1600 IU daily for 12 weeks. Prescribe by brand.

Alternative non-formulary options

Treatment of severe deficiency (25 hydroxyvitamin D level less than 25nmol/l)

- Where an injectable formulation is preferred, consider 300,000IU/ml of intramuscular (IM) ergocalciferol in two injections 3 months apart. This option may be appropriate for those patients who are unable to comply with an oral dosage regimen or if there are concerns about malabsorption. Ergocalciferol injection 300,000IU/ml is licensed and should be used where possible. If unavailable, consider colecalciferol injection 300,000IU/ml (unlicensed alternative) (see Appendix 1).
- If the licensed capsules, oral liquid or injection are unsuitable, as a last resort an unlicensed product may be indicated. For example, preferred 20,000IU containing products suitable for vegetarians are: *Aciferol* 20,000IU tablets or *Sun-Vit* tablets. Products suitable for vegans include: *Sterogyl* (ergocalciferol) 20,000IU/ml or *Steriferol D2* (ergocalciferol) 20,000IU/ml.

Treatment of deficiency associated with disease risk (25 hydroxyvitamin D level 25 to 50 nmol/l)

- Higher strength formulary approved products can be used at a reduced dose.(e.g. *Aviticol* and *Fultium D3* 20,000IU capsules at a dose of 2-3 capsules per month providing a dose of 1400-2000IU/day or *Invita D3* 25,000IU/ml liquid at 25,000IU per month (890IU/day).
- Where an injectable formulation is preferred, consider ergocalciferol injection 300,000IU per ml in a single dose by intramuscular injection once or twice a year. Ergocalciferol injection 300,000IU/ml is licensed and should be used where possible. If unavailable, consider colecalciferol injection 300,000IU/ml (unlicensed alternative) (see Appendix 1).
- If the licensed capsules, oral liquid or injection are unsuitable, as a last resort use an unlicensed product. Products suitable for vegans would be: *Vegan vitamin D2* (ergocalciferol 800IU), *Vitashine vegan Vitamin D3* (1000IU & 500IU) or *Sterogyl* (ergocalciferol 20,000IU/ml).

Maintenance treatment

Maintenance therapy is indicated for:

- Those diagnosed with and treated for severe deficiency (i.e. those with pre-treatment levels of 25 hydroxyvitamin D of <25nmol/l and those with pre-treatment levels of 25 hydroxyvitamin D of between 25-50nmol presenting with severe symptoms and treated with the higher doses of colecalciferol).
- Those with pre-treatment levels of 25-50 nmol/l 25 hydroxyvitamin D or 50-75nmol/l 25 hydroxyvitamin D once deficiency has been corrected, if they are still considered at risk (e.g. housebound patients).
- Preferred products with licensed maintenance doses are tabulated below. Maintenance doses vary according to the products used:

Product	Maintenance dose
Colecalciferol (<i>Aviticol</i>) 20,000IU capsules (Colonis Pharma)	2—3 capsules per month (1400-2000IU/day)
Colecalciferol (<i>Fultium D3</i>) 20,000IU capsules (Internis)	2—3 capsules per month (1400-2000IU/day)
Colecalciferol (<i>Plenachol</i>) 20,000IU capsules	2—3 caps per month (1400-2000) IU/day
Colecalciferol (<i>Desunin</i>) 800IU tablets (Meda)	1-2 tablets daily (800-1600IU/day)
Colecalciferol (<i>Fultium D3</i>) 800IU capsules (Internis)	1-2 capsules daily (800-1600IU/day)
Colecalciferol (<i>InVita D3</i>) oral solution 25,000IU in 1ml (Consilient Health)	25,000IU per month (1ml)
Colecalciferol (<i>Thorens</i>) oral solution 25,000IU in 2.5ml	25,000IU per month (2.5ml)

- Patients who have been successfully treated for vitamin D deficiency for whom prescribed maintenance therapy is not indicated, should be encouraged to make lifestyle changes such as increasing dietary intake of vitamin D, increasing safe sun exposure and increasing vitamin D intake with supplements purchased from community

pharmacies, health food stores or other reputable retailers (see *PACE Bulletin* Vol 6 No 6 Prevention of vitamin D deficiency in at-risk groups (May 2012)).

Cautions and contraindications to vitamin D therapy

Vitamin D supplements should be used with caution in those with primary hyperparathyroidism, renal stones and severe hypercalciuria. Vitamin D is contraindicated in patients with hypercalcaemia or metastatic calcification. For further information refer to the summary of product characteristics (SPC) for each product.

Monitoring requirements

- If pre-treatment levels of 25 hydroxyvitamin D were <25 nmol/l then check 25-hydroxyvitamin D, parathyroid hormone (PTH) and calcium levels, 4 to 6 months after initiation of treatment. At this stage, patients should have been receiving initial high dose treatment for a period of 6 to 8 weeks depending on which product was prescribed and maintenance doses thereafter. If the patient is within reference range there is no need to repeat test. If any of the values are outside of reference range, refer to an endocrinologist.
- Low calcium levels could indicate primary hyperparathyroid disease.
- High calcium levels could be indicative of another underlying condition.
- PTH levels outside of normal range could be indicative of parathyroid disease.
- If pre-treatment levels of 25 hydroxyvitamin D were <50 nmol/l there is no requirement to re-test levels unless symptoms persist following treatment.
- If patients PTH levels were >10 at baseline, re-check at 4 to 6 months regardless of treatment group to exclude the possibility of parathyroid disease. If PTH levels remain elevated whilst vitamin D levels are normal, refer to an endocrinologist.

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4. Summary of Product Characteristics *Fultium-D3* 20,000IU capsules, Internis Pharmaceuticals Ltd. Last Updated on eMC 27-Jan-2015
5. Summary of Product Characteristics *Aviticol* 20 000 IU Capsules, Colonis Pharma Ltd. Last Updated on eMC 23-Dec-2014

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Appendix 1

The information in this table is intended to act as a guide to prescribers as to the range, price and availability of licensed and unlicensed colecalciferol preparations. Information is correct at the time of going to press. Formulary products are highlighted in bold.

VITAMIN D CONTAINING PREPARATIONS (FIRST-LINE CHOICES IN BOLD)				
High dose oral formulations				
PRODUCT NAME AND STRENGTH	MANUFACTURER DISTRIBUTORS	Cost (BNF List price or from manufacturer)	LICENSING	SUITABLE FOR VEGETARIANS or VEGANS
Colecalciferol (Aviticol) 20,000IU capsules (Colonis Pharma)	Available from Quantum Pharmaceutical via normal wholesaler routes.	£29.00(30) (Cost per 40,000IU dose £1.93)	Product has UK marketing authorisation.	Contains gelatine so not suitable for vegetarians or vegans
Colecalciferol (Fultium D3) 20,000IU capsules (Internis)	Available via normal wholesalers routes	£29.00(30) (Cost per 40,000IU dose £1.93)	Product has UK marketing authorisation	Contains gelatine so not suitable for vegetarians or vegans
Colecalciferol (Plenachol) 20,000IU and 40,000IU capsules	Was manufactured by Auden Mckenzie now being transferred to Actavis UK. Available via normal wholesalers routes Any queries on availability 0800 373 573	20,000IU £13.75 (10) 40,000IU £26.50 (10) (Cost per 40,000IU dose £2.65)	Product has UK marketing authorisation	Colecalciferol is derived from sheep's wool fat; manufacturer has confirmed that the product is suitable for vegetarians.
Colecalciferol (InVita D3) oral solution 25,000IU in 1ml (Consilient Health) (1ml plastic ampoules)	Available from Consilient Health via normal wholesaler routes	£4.43 (3 doses) (Cost per 50,000IU dose £2.95)	Product has UK marketing authorisation	Colecalciferol is derived from sheep's wool fat; manufacturer has confirmed that the product is suitable for vegetarians.
Colecalciferol (Thorens) oral solution 25,000IU in 2.5ml	Available from AAH Pharmaceuticals, Alliance and Phoenix	£1.55 (1 x 2.5ml) £5.85 (4 x 2.5ml) (Cost per 50,000IU dose £2.92)	Product has UK marketing authorisation	Colecalciferol is derived from sheep's wool fat; manufacturer has confirmed that the product is suitable for vegetarians.
Colecalciferol (Aciferol D3) 20,000IU tablets	Available from Fontus health via normal wholesaler routes	TBC	Does not have UK marketing authorisation	Colecalciferol is derived from sheep's wool fat; manufacturer unable to confirm if this is from live sheep's wool; confirmed thatv the product is suitable for vegetarians
Colecalciferol (SunVit D3) 20,000IU tablets	Available from www.sunvitds.co.uk	TBC	Does not have UK marketing authorisation	Colecalciferol is derived from sheep's wool fat; manufacturer has confirmed that the product is suitable for vegetarians.
Parenteral products				
Ergocalciferol injection 300, 000 IU/mL (10x1mL)	Available from Focus Pharmaceuticals (Tel. 01283 495 280)	£93.50	Product has UK marketing authorisation	√
Vitamin D3 Streuli Colecalciferol injection 300,000 IU/mL (10x1mL)	Available from IDIS World Medicines, tel. 01932 824 100	£43.50	Does not have UK marketing authorisation. Manufactured and licensed by Streuli Pharmaceuticals,	Colecalciferol is derived from sheep's wool fat and produced synthetically. May not be suitable for

			Switzerland.	vegetarians.
Colecalciferol injection 300,000 IU/ml	Available from Mawdsleys	£12.68	Does not have UK marketing authorisation. Manufactured and licensed in Switzerland.	Colecalciferol is derived from sheep's wool fat; manufacturer has confirmed that the product is suitable for vegetarians. Contains peanut oil.
<i>Ostelin OS</i> ergocalciferol injection 400,000 IU/2ml	Available from UL Medicines (Tel 01923 204 333)	£8.80	Does not have UK marketing authorisation. Manufactured and licensed in Italy.	No information available from supplier. Contains peanut oil.
Lower dose oral formulations				
PRODUCT NAME AND STRENGTH	MANUFACTURER DISTRIBUTORS	Cost (BNF List price or from manufacturer)	LICENSING	SUITABLE FOR VEGTARIANS AND VEGANS
Colecalciferol (<i>Fultium D3</i>) 800IU capsules (Internis)	Available via normal wholesaler routes	£3.60 (30)	Product has UK marketing authorisation	Contains gelatine so not suitable for vegetarians. The gelatine is halal and kosher compliant. Reformulated with maize oil however stocks containing peanut oil may still be in circulation.
Colecalciferol (<i>Desunin</i>) 800IU tablets (Meda)	Available from Meda via the normal wholesaler routes.	£3.60(30)	Product has UK marketing authorisation	Colecalciferol is derived from sheep's wool fat; manufacturer has confirmed that the product is suitable for vegetarians.
Products suitable for vegans				
<i>Vegan vitamin D2</i> (ergocalciferol) 800IU & 2400IU)	Available for purchase from www.devanutrition.com	Price from Vegan supply website 90l - £5.03	Does not have UK marketing authorisation. Marketed as a nutritional supplement	Suitable for vegans
<i>Vitashine vegan</i> (vitamin D3 1000IU & 500IU),	Available for purchase from www.vitashine-d3.com	Website price: 1000IU – 60 day supply - £10.49 2500IU – 60 day supply - £11.49	Does not have UK marketing authorisation. Marketed as a nutritional supplement	Suitable for vegans
<i>Steriferol D2</i> (ergocalciferol solution) 3000IU/ml, 20,000IU/ml	Available from sterling Pharmaceuticals Ltd. Tel 0845 170 5566	C&D 3000IU - 30ml -£29.99 & 60ml – £58.50 20000 IU - 30ml - £29.99	Does not have UK marketing authorisation. Manufactured as a special.	Suitable for vegans
<i>Sterogyl</i> (ergocalciferol)20,000IU/ml	Available from Durbin PLC Tel 020 8869 6554 or UL medicines Tel 01923 204 333	C&D 20ml - £29.85	Does not have UK marketing authorisation. Manufactured and licensed by DB Pharma in France	Suitable for vegans
Liquid formulations				
PRODUCT NAME AND STRENGTH	MANUFACTURER DISTRIBUTORS		LICENSING	SUITABLE FOR VEGTARIANS AND VEGANS
Colecalciferol (<i>InVita D3</i>) oral solution 25,000IU in 1ml (Consilient Health) presented in 1ml plastic ampoules	Available from Consilient healthcare via normal wholesaler routes	£4.43 (3 doses)	Product has UK marketing authorisation	Colecalciferol is derived from sheep's wool fat; manufacturer has confirmed that the product is suitable for vegetarians.

Colecalciferol (<i>Thorens</i>) oral solution 25,000IU in 2.5ml	Available from AAH Pharmaceuticals, Alliance and Phoenix	1.55 (1 x 2.5ml) £5.85 (4 x 2.5ml) (Cost per 50,000IU dose £2.92)	Product has UK marketing authorisation	Colecalciferol is derived from sheep's wool fat; manufacturer has confirmed that the product is suitable for vegetarians.
Colecalciferol drops 10,000 IU/ml 10 ml (<i>Zymad</i>) 30 day expiry after opening	Available from IDIS (Tel 01932 824 100) Mawdsleys (Tel 01302 553 000) UL medicines (Tel 01923 204 333)	IDIS £8.60 Mawdsleys £4.32 UL £6.13	Does not have UK marketing authorisation. Manufactured and licensed by Novartis, France	

*only manufactured on request

Appendix 2

Medicines and Healthcare products Regulatory Agency (MHRA): Hierarchy of risk on basis of product origin (adapted from MHRA guidance)



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