



PAN MERSEY AREA PRESCRIBING COMMITTEE
PRESCRIBING POLICY STATEMENT
REF: PS98 FINAL
FIRST APC BOARD DATE: 05 NOV 2014
LAST APC BOARD DATE: 25 JAN 2017



Pan Mersey

Area Prescribing Committee

LICENSED ORAL COLECALCIFEROL products

GREEN

The Pan Mersey Area Prescribing Committee recommends that where the prescribing of oral COLECALCIFEROL products is deemed appropriate licensed medicines should be prescribed for both adults and children

The Pan Mersey Area Prescribing Committee recommends that, wherever possible, an oral colecalciferol product that is a licensed medicine, within its licensed indications, should be prescribed. Where this is not possible, a licensed medicine used outside its licensed indications i.e. "off-label" should be prescribed.

MHRA guidance states that where a UK licensed product can meet the clinical need it should be used 'off-label' in preference to unlicensed imports, specials and foods for medicinal purpose.¹ The licensed regimens may differ from the regimens in guidelines or recommended by secondary or tertiary care consultants. In these cases, it is advised that the most appropriate licensed medicine to achieve the recommended regimen should be chosen and prescribed outside its licensed indications i.e. "off-label."

Currently available licensed medicines include those listed below. For full details see the relevant Summary of Product Characteristics (SPC.) **Healthy Start Vitamins, Dalivit Drops and Abidec drops should be considered for pregnant women, new mums, babies and young children in line with [DH2011a](#).**

Colecalciferol 25,000 international units in 1ml oral solution unit dose ampoules ([InVita D3](#))

Licensed for both treatment and prevention of deficiency in children aged 0-18 and adults.

Colecalciferol 25,000 international unit tablets ([Stexerol D3](#))

Licensed for both treatment and prevention of deficiency in children over 12 years and adults

Colecalciferol 20,000 international unit capsules (brands available include ([Aviticol](#), [Fultium-D3](#) and [Plenachol](#)))

Licensed for both treatment and prevention of deficiency in children over 12 years and adults.

Colecalciferol 10,000 international units in 1ml oral drops (200 international units in 1 drop) ([THORENS](#))

Licensed for both treatment and prevention of deficiency in children aged 0-18, and prevention in adults and pregnant and breast-feeding women

Colecalciferol 3,200 international unit capsules ([Fultium-D3](#))

NB: Batches manufactured before October 2014 contain arachis (peanut) oil, batches manufactured after this date do not. Patients who need to avoid peanut oil should be advised to check the ingredients listed in the Patient Information Leaflet enclosed in the pack of medicine that they receive.

Licensed for treatment of deficiency in adults and the elderly.

Colecalciferol 2,740 international units in 1ml oral drops (400 international units in 6 drops) ([Fultium-D3 Drops](#))

Licensed for both treatment and prevention of deficiency in children aged 0-18, adults, the elderly and pregnant and breast-feeding women

Colecalciferol 2,400 international units in 1ml oral drops (400 international units in 6 drops) ([Invita D3 oral drops](#))

Licensed for prevention of deficiency in children aged 0-18 and pregnant and breast-feeding women.

Colecalciferol 1,000 international unit tablets ([Stexerol D3](#))

Licensed for both treatment and prevention of deficiency in children over 12 years and adults

Colecalciferol 800 international unit capsules ([Fultium-D3](#))

NB: See note above about arachis (peanut) oil content of batches of Fultium-D3 produced before October 2014.
Licensed for both treatment and prevention of deficiency in children over 12 years, adults (including pregnant and breastfeeding women) and the elderly.

Colecalciferol 800 international unit tablets ([Desunin](#))

Licensed for both treatment and prevention of deficiency in adults and adolescents.

Note: Patients who are not eligible for treatment under this policy may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy. If appropriate an exceptional funding request will be required following the usual locally defined process.

LICENSED ORAL COLECALCIFEROL products

<p>EFFECTIVENESS</p> <p>The Pan Mersey Vitamin D Guidelines are currently under review. There are Department of Health recommendations and National Guidance which give differing definitions of deficiency and insufficiency and differing recommendations of doses required to correct and maintain appropriate levels dependent on the patient. Please consult the following for further information:</p> <ul style="list-style-type: none"> • NICE maternal and child nutrition (PH 11) • NICE Antenatal Care (CG 62) • NICE Falls: assessment and prevention of falls in older people (CG 161) • National Osteoporosis Society: Vitamin D and Bone Health: A Practical Clinical Guideline for Patient Management http://www.nos.org.uk/document.doc?id=1352 • Delivering a healthy start for pregnant women, new mums, babies and young children DH2011a • Vitamin D – advice on supplements for at risk groups (Chief Medical Officers 2012) • Guide for Vitamin D in Childhood (RCPCH 2013) • NICE has published Public Health Guidance, Vitamin D: increasing supplement use among at-risk groups, published November 2014 PH56 	<p>SAFETY</p> <p>Please refer to individual SPC links.</p> <p>Contraindications: hypersensitivity to vitamin D or any of the excipients, hypervitaminosis D, nephrolithiasis, diseases or conditions resulting in hypercalcaemia and/or hypercalciuria, severe renal impairment or pseudohypoparathyroidism (other forms of vitamin D should be used)</p> <p>Undesirable effects include hypercalcaemia; and hypercalciuria which are listed as uncommon. Use with caution in patients suffering from sarcoidosis due to risk of vitamin D in its active form and calcium content should be monitored in the urine.</p> <p>Use with caution in those receiving treatment for CVD.</p>																				
<p>COST²</p> <p>Loading dose cost is per course of 300,000 international units, given either as weekly or daily split doses³</p> <p>Adult maintenance and paediatric dose costs are per annum.</p> <p><u>For typical adult loading dose (300,000 international units over a short period)</u></p> <table> <tr> <td>Fultium D3[®] or Avitcol[®] 20,000 international units caps</td><td>£14.50</td></tr> <tr> <td>Stexerol D3[®] 25,000 international unit caps</td><td>£17.00</td></tr> <tr> <td>InVita D3[®] 25,000 international units per ml</td><td>£17.80</td></tr> </table> <p><u>For typical adult maintenance dose (800-1,000 international units daily or 20,000 – 25,000 international units monthly)</u></p> <table> <tr> <td>Fultium D3[®] or Avitcol[®] 20,000 international units caps</td><td>£11.60</td></tr> <tr> <td>Stexerol D3[®] 25,000 international unit caps</td><td>£17.00</td></tr> <tr> <td>InVita D3[®] 25,000 international units per ml</td><td>£17.80</td></tr> <tr> <td>Stexerol D3[®] 1,000 international unit caps</td><td>£38.46</td></tr> <tr> <td>Desunin[®] or Fultium D3[®], 800 international units tabs/caps</td><td>£43.80</td></tr> </table> <p><u>For typical paediatric doses (200 – 1,500 international units daily)</u></p> <table> <tr> <td>THORENS 10,000 international units in 1ml oral drops</td><td>£ 4.27 - £32.03</td></tr> <tr> <td>Fultium D3[®] oral drops or Invita D3[®] oral drops</td><td>£10.95 - £82.15</td></tr> </table>	Fultium D3 [®] or Avitcol [®] 20,000 international units caps	£14.50	Stexerol D3 [®] 25,000 international unit caps	£17.00	InVita D3 [®] 25,000 international units per ml	£17.80	Fultium D3 [®] or Avitcol [®] 20,000 international units caps	£11.60	Stexerol D3 [®] 25,000 international unit caps	£17.00	InVita D3 [®] 25,000 international units per ml	£17.80	Stexerol D3 [®] 1,000 international unit caps	£38.46	Desunin [®] or Fultium D3 [®] , 800 international units tabs/caps	£43.80	THORENS 10,000 international units in 1ml oral drops	£ 4.27 - £32.03	Fultium D3 [®] oral drops or Invita D3 [®] oral drops	£10.95 - £82.15	<p>PATIENT FACTORS</p> <p>Caution in renal impairment (monitor calcium and phosphate levels). The risk of soft tissue calcification should be taken into account.</p> <p>There are limited data on the use of high-doses of colecalciferol in pregnant women. For this reason, only licensed products at licensed doses should routinely be prescribed for this patient population.</p>
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PRESCRIBING INFORMATION

Unless advised differently by the specialist for an individual patient, adjusted serum calcium should be checked 1 month after starting treatment or if a loading regimen is prescribed, 1 month after completion of the loading regimen.³

Desunin tablets can be swallowed whole or crushed.

IMPLEMENTATION NOTES

Vitamin D deficiency or insufficiency can be diagnosed and treated in primary, secondary or tertiary care. If prescribing is initiated in secondary or tertiary care, it is recommended that a clear plan of dosage and timescales is clearly documented in the patient's medical notes and communicated to primary care.

REFERENCES

1. MHRA. Guidance Note 14. The supply of unlicensed medicinal products ("specials") [Supply unlicensed medicinal products \(specials\) - Publications - GOV.UK](#) accessed 26/09/16
2. Drug Tariff Online. Accessed 19/10/16 [Drug Tariff Online](#)
3. National Osteoporosis Society. Vitamin D and Bone Health: A Practical Clinical Guideline for Patient Management: accessed 26/09/16 [NOS2013](#)