

## **High dose Vitamin D information sheet for prescribers and pharmacies: Victoria, June 2009**

**Please direct queries about the information contained as follows:**

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Western Health  
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**Paediatric:** Dr Georgia Paxton Medical Coordinator Immigrant Health Service  
Royal Children's Hospital  
[georgia.paxton@rch.org.au](mailto:georgia.paxton@rch.org.au)

**General:** Sally Richardson Senior Policy Advisor Refugee Health  
Department of Human Services  
[sally.richardson@dhs.vic.gov.au](mailto:sally.richardson@dhs.vic.gov.au)

### **Cal.D.Forte High Dosage Vitamin D**

#### **Prescribing arrangements**

- Cal.D.Forte is an unregistered (S4) product in Australia. As such it can only be obtained under the Special Access Scheme (SAS) or as an authorised prescriber PBAC Section 19(5) of the *Therapeutic Goods Act 1989* (see References section at end).
- In partnership with Western and Royal Melbourne Hospitals, some General Practitioners local to the two hospitals are now authorised prescribers of Cal.D.Forte.
- Cal.D.Forte tablets contain 1.25mg of cholecalciferol and are white sugar coated.
- Cal.D.Forte Data sheet (see References section below)
- Frequently asked questions for authorised prescribers (see References section below)

#### **Halal certification**

- The lactose and gelatine excipients contained in Cal.D.Forte are both Halal certified
- There is no alcohol used in Cal.D.Forte.

#### **Reporting requirements for prescribers**

- Authorised prescribers need to provide a **quarterly report** to the TGA detailing:
  - the number of patients *commenced* on cholecalciferol treatment
  - the number of patients *continued* on treatment (ie given a repeat prescription).
- See attached **TGA reporting table** and references section for more information.
- **Reporting of adverse events.** Adverse events, adverse drug reactions, unexpected adverse drug reactions must be reported to the TGA within 15 days of first knowledge (See references section below for link to more information).

#### **Reporting requirements for pharmacies acting as sponsors**

- As sponsors, community pharmacies receiving the imported tablets must
  - maintain records of receipt and supply of the tablets. This information may or may not be asked for by the TGA in the future
  - report any adverse events as per GPs above.

## Cal.D.Forte High Dosage Vitamin D: Adult dosing

- Need to distinguish between **mild** and **severe deficiency** when determining dose.
- Most patients will need between 1,000 to 2,000 IU a day as a rough guide.
- **Pregnancy:** 1,000 a day then high dosage post partum. Do not use preparations containing Vitamin A which may lead to foetal toxicity.
- **Toxicity:** it is not recommended to prescribe more than 600,000 IU in a single dose.
- **Calcium:** A calcium intake of 1200 mg per day is also recommended.

ADULT Vitamin D level nmol/L	High dosage vitamin D required?	ADULT Loading dose required?	ADULT Dose vitamin D	ADULT Testing regimen	ADULT Clinical notes
INSUFFICIENCY 50-75	NO	NO	400-1000 IU/ day	Recheck vitamin D level at 3 mths then every 12 mths	Aim for target of 50-75 nmol/L
MILD 25-50	YES	NO	50,000 IU/ mth	Recheck vitamin D level at 3 mths then every 12 mths	Aim for target of 50-75 nmol/L
MOD 12.5-25	YES	YES, 1 tab a day for 10 days (total 500,000 IU)	50,000 IU/ mth	Recheck vitamin D level at 3 mths then every 12 mths	Aim for target of 50-75 nmol/L
SEVERE <12.5	YES	YES, 1 tab a day for 10 days (total 500,000 IU)	50,000 IU/ mth	Recheck vitamin D level at 3 mths then every 12 mths	Aim for target of 50-75 nmol/L

## Cal.D.Forte High Dosage Vitamin D: Paediatric dosing

The **current position statement** on the Prevention and treatment of infant and childhood Vitamin D deficiency in Australia and New Zealand<sup>1</sup> states that > 50 nmol/L is the desired level.

**Dosing** see following table

- The current Australian consensus statement for infants and children uses treatment of 500,000 IU oral over 1-7 days for children aged > 12 months with low vitamin D. A **lower treatment dose is suggested in these guidelines** given the issues with off label prescribing, follow-up and monitoring for adverse effects in the primary care setting.

**Monitoring** after starting Vitamin D treatment:

- At 3 months: serum calcium, phosphate, alkaline phosphatase, 25 OH vitamin D, parathyroid hormone
- Annual: 25 OH vitamin D and ALP
- Once treatment has restored Vitamin D levels, aim to maintain Vitamin D > 50 nmol/L.
- Review Vitamin D level 3 months after initial treatment; further dosing may be required. Some children may require dosing more often than once a year to maintain adequate Vitamin D levels.

**High dosage tablets are crushable.** They can be chewed or mixed with sandwich spreads/jam if needed for children.

**Calcium supplementation** is recommended if dietary intake is poor (see table below).

**Urgent specialist referral indicated**

- Abnormal serum calcium (high or low)
- Clinical rickets
- No response after 2 doses of vitamin D (high dose regimen)

**Contact details for specialists**

Royal Children's Hospital Immigrant health Clinic: 9345 5522, [helen.milton@rch.org.au](mailto:helen.milton@rch.org.au)

Dandenong Hospital Refugee Clinic:

Western Region Health Centre Specialist vitamin D clinic:

Darebin Community Health Centre Specialist vitamin D clinic:

**Calcium requirements in children and adolescents<sup>2</sup>**

Age	RDI calcium**
< 6 months	210 mg/day
7-12 months	270 mg/day
1-3 years	500 mg/day
4-8 years	700 mg/day
9-11 years	1000 mg/day
12-18 years	1300 mg/day

*Note:* 1 cup cow milk contains ~ 300 mg calcium. Calcium supplements contain variable amounts of elemental calcium (check product information and cost); they can be dissolved in a tablespoon of hot water for administration to young children if needed.

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\*\* RDI (Recommended Dietary Intake) The average daily dietary intake level that is sufficient to meet the nutrient requirements of nearly all (97–98 per cent) healthy individuals in a particular life stage and gender group.

## Cal.D.Forte High Dosage Vitamin D: Paediatric dosing

### Neonate (age < 1 month)

Vit D level nmol/L	High dose vitamin D required?	Treatment	Maintenance	Testing regimen	Clinical notes
MILD 25-50	NO	400 IU daily	400 IU daily	3 months then annual	Neonates/Infants are at higher risk of hypocalcaemic seizures
MOD 12.5-25 OR SEVERE <12.5	NO	1,000 IU daily for 3 months			

### Infant (age 1 – 12 months)

Vit D level nmol/L	High dose vitamin D required?	Treatment	Maintenance	Testing regimen	Clinical notes
MILD 25-50	MAY BE USED	400 IU daily for 3 months <sup>1</sup> or 50,000 IU stat	400 IU daily	3 months then annual	Neonates/Infants are at higher risk of hypocalcaemic seizures
MOD 12.5-25 OR SEVERE <12.5	MAY BE USED	1,000 IU daily for 3 months or 100,000 IU stat			

### Children and adolescents (1 – 18 years)

Vit D level nmol/L	High dose vitamin D required?	Treatment	Maintenance	Testing regimen	Clinical notes
MILD 25-50	MAY BE USED	1,000-2,000 IU daily for 3 months or 150,000 IU stat	400 IU daily or 150,000 IU at start of autumn <sup>2</sup>	3 months then annual	
MOD 12.5-25 OR SEVERE <12.5	MAY BE USED	1,000 – 2,000 IU daily for 6 months or 150,000 IU stat and repeat at 6 weeks			

<sup>1</sup> If an infant has low vitamin D levels *despite* daily dosing use the high dose option

<sup>2</sup> Once treatment has restored Vitamin D levels, aim to maintain Vitamin D > 50 nmol/L; some children may require dosing more frequently to maintain Vitamin D levels. Review Vitamin D level 3 months after initial treatment; further dosing may be required.

## Available vitamin D oral preparations at June 2008

For GPs not authorised to prescribe Cal.D.Forte or who wish to prescribe a daily dose vitamin D product, the following products are known and vary in price.

Name	Strength	Cost (approximate)	Approx cost per month
<b>HIGH DOSE</b>			
Cal.D.Forte	50,000 IU tablets	\$25/12	\$2.00
RCH Vitamin D3 in olive oil	100,000 IU/ml	\$13/200 ml	a few cents
<b>DAILY</b>			
Blackmores	1,000 IU capsules	\$12/60	\$6.00
Blooms	1,000 IU capsules	\$10/60	\$5.00
OsteVit-D	1,000 IU tablets	\$14/90	\$4.60
		\$35/250	\$4.20
Ostelin	1,000 IU capsules	\$15/60	\$7.50
		\$49/250	\$5.90
Penta-vite	400 IU/0.45 ml	\$6/20 ml syrup	\$4.00
	syrup	\$14/50 ml syrup	\$3.80
		0.45ml/d	
		13.5ml/month)	

Cod liver oil capsules are not suitable for Vitamin D replacement, as they typically contain 60 - 85 IU of vitamin D per capsule but 8 - 10 times more vitamin A per capsule. The amount of capsules required to provide adequate daily vitamin D would *exceed* the RDI for Vitamin A and may lead to toxicity.

## References and resources

Cal.D.Forte datasheet: Information for health professionals  
[www.medsafe.govt.nz/profs/datasheet/c/CalDFortetab.htm](http://www.medsafe.govt.nz/profs/datasheet/c/CalDFortetab.htm)

Frequently asked questions for authorised prescribers  
[www.tga.gov.au/hp/apfaq.htm#notify](http://www.tga.gov.au/hp/apfaq.htm#notify)

Reporting of adverse outcomes. See page 23 onwards of  
[www.tga.gov.au/docs/pdf/unapproved/authpres.pdf](http://www.tga.gov.au/docs/pdf/unapproved/authpres.pdf).

Munns C, Zacharin MR, Rodda CP, et al. Prevention and treatment of infant and childhood vitamin D deficiency in Australia and New Zealand: a consensus statement. Med J Aust 2006;185(5): 268-72 [www.mja.com.au/public/issues/185\\_05\\_040906/mun10153\\_fm.html](http://www.mja.com.au/public/issues/185_05_040906/mun10153_fm.html)

Nutrient Reference Values for Australia and New Zealand. Australian Government. National Health and Medical Research Council. [www.nrv.gov.au/Nutrients.aspx](http://www.nrv.gov.au/Nutrients.aspx)

*Promoting refugee health. A guide for doctors and other health care providers caring for people from refugee backgrounds.* Foundation House 2007 [www.foundationhouse.org.au](http://www.foundationhouse.org.au)

## Authorized Community pharmacy partners

### **BRIMBANK:**

Deer Park Pharmacy  
811a Ballarat Rd  
Deer Park VIC 3023  
Pharmacist is Chris Luu  
Ph: 9363 1026  
Fax: 9306 1221

### **WYNDHAM:**

Quality Pharmacy Werribee  
Shop T 109 Werribee Plaza  
Derrimut Rd  
Hoppers Crossing VIC 3029  
Pharmacist: Fred Najjar  
Ph: 9749 3332  
Fax: 9749 2223

### **DAREBIN:**

National Pharmacy  
870 Plenty Rd  
East Reservoir VIC 3073  
Pharmacist: Judy Dent  
Ph: 9478 0939  
Fax: 9479 9179

### **MOONEE VALLEY/ MELBOURNE**

Irvine Newton or Bronwyn Flanagan  
477 Macaulay Rd  
Kensington VIC 3031  
Pharmacist: Irvine Newton/ Bronwyn Flanagan  
Ph: 9376 2022

### **MOONEE VALLEY**

Ascot Vale Pharmacy  
67-69 Union Rd  
Ascot Vale VIC 3032  
Co-owners Dimitra Tsucalas & Jane Mitchelle  
Ph: 9370 4146

### **YARRA:**

North Yarra Community Health Pharmacy  
365 Hoddle St  
Collingwood VIC 3066  
Pharmacist: Katrine Harper and Le Duan Anh Lee  
Ph: 9411 4314

### **YARRA:**

Perry Moshidis Pharmacy  
Shop 22  
246 Church Street  
Richmond VIC 3121  
Pharmacist: Perry Moshidis  
Ph: 9428 3640  
Fax: 9428 3640

### **YARRA:**

David Nolte Pharmacy  
701 Rathdowne St  
Nth Carlton VIC 3054  
Ph: 9349 1522  
Fax: 9349 1115  
Website: [www.nolte.com.au](http://www.nolte.com.au)

### **MARIBYRNONG:**

Paisley Clinic Pharmacy  
85 Paisley Street  
Footscray VIC 3011  
Pharmacist: Khai T Nguyen  
Ph: 9689 3220  
Fax: 9396 1423  
Website: [paisleyclinic.pharmacy@nUNET.com.au](mailto:paisleyclinic.pharmacy@nUNET.com.au)

## Authorized Clinics

<b>CLINIC NAME</b>	<b>ADDRESS 1</b>	<b>ADDRESS 2</b>	<b>Telephone</b>
Holistic Health House	126 Jukes Road	Falkner, 3060	9359 0655
Summerhill Medical Centre	2a, 830 Plenty Rd	Reservoir 3073	9471 3788
North Richmond Community Health Centre	23 Lennox St	Richmond 3121 Collingwood	9429 5477
North Yarra Community Health	365 Hoddle Street	3066	9411 4333
North Yarra Community Health	75 Brunswick Street	Fitzroy 3065	9411 3555
West Heidelberg Medical Holdings	Shop 64 The Mall West	Heidelberg 3081	9459 5400
Flemington Medical Centre	9 Princes St	Flemington 3031	9376 6884
Macaulay Road Family Medical Centre	475 Macaulay Rd	Kensington 3031	9376 4108
Western Hospital	22 Eleanor St	Footscray 3011	9318 1722
Sunshine Hospital,	Furlong Road,	St Albans 3021	83451330
Western Hospital	Gordon Street,	Footscray 3011 North Carlton	8345 6666
Carlton Medical Centre	488 Rathdowne St 1st Floor, 333 Drummond St	3054	9380 4655
Metropolitan Medical Centre	St	Carlton 3053 West Melbourne	9347 7711
Asylum Seeker Resource Centre	12 Batman Street	3003	9326 6066
Complete Family Care	471 Melbourne Rd	Newport 3015	9391 0033
The Medical Centre	259-265 Geelong Rd	Kingsville 3012	9687 7258
Sunshine Ultimate Care Clinic	127 Durham Rd	Sunshine 3020 Hoppers Crossing	9939 6741
ISIS Primary Care	117-129 Warringa Crescent	3029 Altona Meadows	8734 1400
Meadows Medical Centre	311 Queen Street	3028	9369 4266
Westcare Medical Centre	1/211 Barries Rd	Melton 3337	9747 5800
The Clinic Medical Practice	106 Station Road	Deer Park 3023	9219 7142
Braybrook Community Health Centre	107-139 Churchill Avenue	Braybrook 3019	9364 9622
Western Region Health Centre	72 Paisley street	Footscray 3011	8398 4100
The Clinic Footscray	91 Paisley street	Footscray 3011	9687 2271
Ascot Vale Health Group	73 Union Road	Ascot Vale 3032 East Reservoir	9370 3322
Darebin Community Health	125 Blake street	3073	8470 1109
Millennium Medical centre	Cnr Paisley & Albert St	Footscray 3011	9687 8633

**TGA Authorised Prescriber Quarterly Report  
Supply of Unregistered Drugs**

Quarterly report by a prescriber authorised under Subsection 19(5) of the *Therapeutic Goods Act 1989* (please write name)

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**Report for the quarter ending (please circle one)**

31 March

30 June

30 September

31 December

**DRUG: Cholecalciferol**

**Number of new patients commenced on treatment (ie given initial prescription)**

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**Number of patients continued on treatment (ie given repeat prescription)**

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**Signature** .....

**Date**.....

Please send this report to:

Drug Safety & Evaluation Branch Therapeutic Goods Administration PO Box 100 Woden ACT 2606
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