MONOGRAPH

COLECALCIFEROL

Scope (Staff):	Medical, Pharmacy, Nursing
Scope (Area):	All Clinical Areas

Child Safe Organisation Statement of Commitment

CAHS commits to being a child safe organisation by applying the National Principles for Child Safe Organisations. This is a commitment to a strong culture supported by robust policies and procedures to reduce the likelihood of harm to children and young people.

This document should be read in conjunction with this DISCLAIMER

QUICKLINKS

Dosage/Dosage Adjustments	Administration	Monitoring

DRUG CLASS[1]

Vitamin D

INDICATIONS AND RESTRICTIONS[1]

Some formulations are special access scheme products. SAS application(s) must be completed in accordance with the TGA regulations.

Indications

- Prevention and treatment of vitamin D deficiency
- Hypocalcaemia in hypoparathyroidism, hypophosphataemic rickets, renal osteodystrophy, chronic renal dialysis
- Secondary hyperparathyroidism associated with chronic kidney disease
- Treatment of osteoporosis
- Prevention of corticosteroid-induced osteoporosis

Restrictions

- Oral liquid 1000 unit/drop (25,000 units/mL) BioCeuticals® D3 Drops Forte, 1250 microgram (50,000 unit) capsules and 2.5 mg/mL ampoule (100,000 units/mL) are used for single high

dose colecalciferol therapy ("Stoss" therapy) only and are restricted to administration during an outpatient clinic visit or as an inpatient.

CONTRAINDICATIONS[1, 12]

- Hypersensitivity to colecalciferol or any component of the formulation.
- Vitamin D is contraindicated in patients with malabsorption syndrome.
- Hypercalcaemia or colecalciferol toxicity.

PRECAUTIONS[1,2]

- Hyperphosphataemia.
- Patients with renal impairment, calculi or heart disease who may be at increased risk of organ damage if hypercalcaemia occurred.

FORMULATIONS

NOTE: Colecalciferol is not to be confused with calcitriol. Calcitriol is the active form of vitamin D and is NOT covered by this monograph.

Listed below are products available at PCH, other formulations may be available, check with pharmacy if required:

- Capsule: 25 microgram (1000 units)
- Tablet: 12.5 microgram (500 units) with calcium carbonate 1.5 g (equivalent to 600 mg of elemental calcium).
- Liquid: 1000 units/0.2 mL (5000 units/mL)
- Ampoule: 2.5 mg/mL (100,000 units/mL)
  This is a SAS product (see "Indications and Restrictions" above).
- VitABDECK capsules: each capsule contains Vit A 2500 units, betacarotene 3 mg, total retinol equivalents 1250 microg, vit B1 1.5 mg, B2 1.7 mg, B6 1.9 mg, B12 3 microg, niacin 20 mg, biotin 100 microg, folic acid 0.2 mg, vit C 100 mg, pantothenic acid 12 mg, vit D 11 microg (440 units), vit E 150 units, vit K 150 microg, zinc 7.5 mg

Access to the following 2 items is RESTRICTED due to their higher strength and potential for errors in administration:

- Capsule: 1250 microgram (1.25 mg, 50,000 units)
  NOTE: This is 50 times stronger than the standard capsule strength described above.
- Liquid: 1000 unit/drop (BioCeuticals® - D3 Drops Forte). This is equivalent to 25,000 units/mL.
  NOTE: This is 5 times more concentrated than the standard liquid strength described above.

Imprest location: Formulary One

DOSAGE & DOSAGE ADJUSTMENTS[1, 3, 4, 5, 6, 8, 14]

Neonates: Refer to Neonatal Medication Protocols

NOTE: High dose treatment ("Stoss" therapy) should not be used in patients less than 3 months old.

Oral dosing is preferred, and intramuscular administration should only occur on specialist advice.

Colecalciferol levels must be normal prior to commencing a bisphosphonate infusion. For suggested colecalciferol dosing, see table below. Patients with normal serum calcium/ vitamin D levels and at low risk of bisphosphonate-related hypocalcaemia may be exempted from pre-infusion calcium/colecalciferol supplementation at the treating consultant's discretion. See bisphosphonate monographs pamidronate and zoledronic acid for more information including duration of treatment.

Non-Cystic fibrosis patients

Age	**Treatment for severe deficiency** (<12.5 nanomol/L) **and moderate deficiency** (12.5-29 nanomol/L)	**Treatment for mild deficiency** (30-49 nanomol/L)	**Maintenance/ prevention in children with ongoing risk factors**
<3 months	Oral: 1000 units/day for 3 months	Oral: 400 units/day for 3 months	Oral: 400 units/day
3-12 months	Oral: 1000 units/day for 3 months **OR** *Oral/IM: 50,000 units stat, review after 1 month, consider repeating dose	Oral: 400 units/day for 3 months	Oral: 400 units/day
1-18 years	Oral: 1000-2000 units/day for 6 months **OR** Oral: 3000-4000 units/day for 3 months **OR** *Oral/IM: 150,000 units stat and repeat at 6 weeks	Oral: 1000-2000 units/day for 3 months **OR** *Oral/IM: 150,000 units stat	Oral: 400-600 units/day **OR** *Oral/IM: 150,000 units at the start of autumn

*Single high dose treatment ("Stoss Therapy"), should only be used where risk of non-compliance is thought to be high or in specific patient groups e.g. Cystic Fibrosis (CF). Repeat doses can be given after 6-12 weeks depending on clinical situation.

Cystic fibrosis patients

For CF patients with pancreatic insufficiency, a higher dose of colecalciferol is recommended to ensure supplementation is sufficient.

Treatment of moderate to severe deficiency for patients with Cystic Fibrosis

Oral/IM dosing:

Age	≤ 25 nanomol/L	25 - 50 nanomol/L	50 – 75 nanomol/L
< 3 years	200,000 units stat	150,000 units stat	100,000 units stat
3 - 12 years	400,000 units stat	350,000 units stat	200,000 units stat
> 12 years	600,000 units stat	500,000 units stat	300,000 units stat

Maintenance dose for patients with Cystic Fibrosis

Oral dosing:

Age	Vit ABDECK® dose	Additional colecalciferol dose	Recommended daily dose [3,5,6]	Total daily dose
Birth–12 months	½ capsule (220 units)	500 units	400-500 units	720 units
1 – 3 years	½ capsule (220 units)	1000 units	800-1000 units	1220 units
3 – 10 years	1 capsule (440 units)	1000 units	800-1000 units	1440 units
10 years and over	2 capsules (880 units)	1000 units	1500-2000 units	1880 units

Renal impairment:

- eGFR calculator
- Avoid use in severe impairment; as these patients may not be able to convert colecalciferol to the active form of Vitamin D. Children with Chronic Kidney Disease (CKD) should receive alternative Vitamin D supplementation. Contact a Renal Consultant for advice.

Hepatic impairment:

- No dose adjustments required.

Patients with malabsorption, dark skin, who are obese, or are taking interacting drugs may need higher doses.

ADMINISTRATION [9, 11]

ORAL

- Colecalciferol can be given orally with or without food.
- Adequate calcium intake is necessary for clinical response.
- BioCeuticals® D3 Drops Forte is an emulsion and needs to be shaken before each dose is withdrawn.

INTRAMUSCULAR (IM)

- Suitable. Inject undiluted slowly into the gluteal muscle. The ventrogluteal site is preferred.
- Intramuscular administration should be in accordance with the Intramuscular (IM) Injections Procedure.

MONITORING[1, 9, 10, 3]

Targeted measurement of colecalciferol levels is recommended for infants, children and adolescents with at least one risk factor for low colecalciferol. Risk factors for low colecalciferol are:

- Lack of skin exposure to sunlight
- Dark skin
- Southerly latitude
- Conditions affecting colecalciferol metabolism and storage (including obesity, cystic fibrosis, renal disease)
- Medications affecting colecalciferol (certain anticonvulsants)
- For infants, being born to a mother with low colecalciferol and exclusive breastfeeding combined with at least one other risk factor

Wait at least 3 months after starting supplements before re-testing serum colecalciferol concentration. Repeat at 3 monthly intervals until normal.
Parathyroid hormone and bone mineral status should be monitored every 6 months until normal.
After "*Stoss Therapy*": Recheck colecalciferol, calcium, magnesium, phosphate, parathyroid hormone and alkaline phosphatase after 1 month and 3 months.

For Chronic Kidney Disease: Colecalciferol, corrected calcium and phosphate levels should be monitored 1 month following imitation of therapy and then at least every 3 months. Alkaline

phosphatase and blood urea nitrogen should also be measured following in change in colecalciferol dose. Contact a Nephrologist for further advice.

For Rickets: Check colecalciferol, corrected calcium, phosphate and alkaline phosphatase (and parathyroid hormone if previously elevated) at 1 month in infants and at 3 months in older children.

ADVERSE EFFECTS[1, 2 ,8]

Common: Abdominal pain; headache; hypercalcaemia; hypercalciuria; nausea; skin reactions.

Infrequent: Appetite decreased; asthenia; constipation; diarrhoea; myalgia; vomiting.

Rare: See below.

When given at supplementary doses, colecalciferol is not generally associated with serious adverse reactions.

Most adverse effects result from hypercalcaemia. Symptoms of hypercalcaemia include nausea, vomiting, constipation, anorexia, apathy, muscle weakness, headache, thirst and polyuria. Mild, non-progressive and reversible elevations of LFTs occasionally occur.

Renal and cardiovascular damage may occur because of ectopic calcification.

STORAGE

- Capsule 25 microgram (1000 units): store below 25°C
- Tablet 12.5 microgram (500 units) + calcium carbonate 1.5g (equivalent to 600 mg of elemental calcium): store below 25°C
- Liquid: 1000 units/0.2 mL (5000 units/mL): store below 25°C
- Ampoule: 2.5 mg/1 mL (100,000 units/mL): store below 25°C
- Capsule: 1250 microgram (1.25 mg, 50,000 units): store below 25°C
- Liquid: 1000 unit/drop (BioCeuticals® - D3 Drops Forte) store below 25°C, refrigerate after opening.

INTERACTIONS

This medication may interact with other medications; consult PCH approved references (e.g. Clinical Pharmacology), a clinical pharmacist or PCH Medicines Information Service on extension 63546 for more information.

Please note: The information contained in this guideline is to assist with the preparation and administration of **Colecalciferol.** Any variations to the doses recommended should be clarified with the prescriber prior to administration

Related CAHS internal policies, procedures and guidelines

Intramuscular (IM) Injections

Pamidronate

Zoledronic acid

References

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Useful resources (including related forms)

D3-Vicotrat ampoules - Product Information (English)

This document can be made available in alternative formats on request for a person with a disability.

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