VITAMIN D – COLECALCIFEROL

Trade Name	Clinicians® Vitamin D drops (Douglas Nutrition NZ)[1]
Class	Fat soluble vitamin[2]
Mechanism of Action	Promotes calcium and phosphate absorption from the small intestine, facilitates secretion of calcium from bone to blood and aids absorption of phosphate in the renal tubules. It also acts directly on osteoblasts to stimulate skeletal growth and on the parathyroid gland to suppress synthesis and secretion of parathyroid hormone.[3,4]
Supplied As	Per Drop: 400 IU/drop or 10mcg/drop. 90 drops per bottle Per mL: 7500 IU/mL or 188mcg/mL
Indication	1. < 37 wks or < 2500 g at birth as prophylaxis for Vitamin D deficiency 2. ≥37 weeks high risk term babies if: o Breastmilk fed ▪ over winter (April – October) o Breastmilk or formula fed with: ▪ naturally dark skin ▪ a mother with vitamin D deficiency ▪ a sibling who has had rickets or seizures from low blood calcium levels 3. Chlestasis or malabsorption as prophylaxis for Vitamin D deficiency 4. Treatment of documented vitamin D deficiency
Dosage …	1. Babies **<35 weeks** gestation to start **2 drops/day** (800 IU) and reduce to **1 drop/day at discharge** if there have been no need for dose alterations during the admission Babies **≥35 weeks** gestation, **1 drop/day** (400 IU) and to discharge on this dose o Start when on enteral feeds or the day after lipid finishes o Continue until a year of age o Babies on unfortified EBM, specialised term formula or hydrolysed formula, (which may have much lower levels of vitamins and minerals or fluid restricted to < 150 mL/kg/day may need individual assessment of vitamin D intake. Discuss with the dietitian. 2. **High risk breastfed term** babies, **1 drop/day** (400 IU) o Continue until a year of age

… Dosage	3. **Cholestasis or malabsorption**, 0.5mL (3750 IU) until the conjugated bilirubin has normalised and GGT< 100 (the level of conjugated bilrirubin to stop supplementation needs to be individualised and d/w Prof Andrew Day). The dose is between 9-10 drops but for ease of administration draw up from the vial with a syringe. 4. **Confirmed Vitamin D deficiency (Level <50 nmol/L)** **First level <40 nmol/L** – increase from 2 to 6 drops daily **First level 40-49 nmol/L** – increase from 2 to 4 drops daily **Check levels 2 weekly and alter dose as below:** If < 50 nmol/L – increase dose by 2 drops If 50-99 nmol/L – no change to dose, or, reduce dose by 2 drops daily if the rise has been rapid If 100-150 nmol/L – reduce dose by 2 drops If >150 nmol/L – decrease to 1 drop daily Stop monitoring levels when on 1 or 2 drops a day with a level in the normal range of 50-150 nmol/L
Administration	 The Puria bottle will be named and used for only one baby. NB. Do not shake the bottle Can be given: • Added to an enteral or bottle feed (preferred suggestion) • Put a drop on your gloved finger and then into baby's mouth • As a drop directly onto baby's tongue or into mouth[1] **Larger Doses for Cholestasis:** The bung can be removed and the dose drawn up by syringe. Keep the vial upright as with the bung removed there can be leakage.
Contraindications	Hypersensitivity to colecalciferol Hypercalcaemia Hypervitaminosis D Metabolic disorders of lipid metabolism
Compatible with	Do not mix with other medication
Incompatible with	Do not mix with other medication

Interactions	Increased risk of hypercalcaemia if colecalciferol is administered in combination with thiazide diuretics (eg chlorothiazide). Potential for increased requirements for vitamin D in patients requiring longterm treatment with certain anti epileptic medications (eg. carbamazepine, phenobarbital, phenytoin).
Monitoring	Routine monitoring is not usually required for most neonates **Criteria to take routine Vitamin D levels**: o <28 weeks – take first level at 4 weeks of age o Confirmed Vitamin D deficiency - check levels 2 weekly o Cholestatic liver disease – check levels 4 weekly 25- hydroxyvitamin D, calcium and phosphate, parathyroid hormone and alkaline phosphatase may be useful indicators of vitamin D status.
Stability	Discard 3 months after opening or as per manufacturers expiry if shorter.
Storage	Store at room temperature, no need for refrigeration after opening.
Adverse reactions	Incidence of adverse effects from exposure to vitamin D is unknown. Puria® is not expected to cause adverse effects and does not contain any sweeteners, colours, flavours or preservatives. (Hypervitaminosis D (overdose of vitamin D) is associated with nausea, vomiting, lethargy confusion,polydipsia, polyuria, cardiac arrhythmia, soft tissue calcification, calciuria and nephrocalcinosis).
Metabolism	Hydroxylated in the liver, xcreted by the kidneys,half life 9-25hrs
Comments	The European Society for Paediatric Gastroenterology Hepatology and Nutrition (ESPGHAN) 2014[5] recommends 800- 1000 IU colecalciferol per day. The exact dose requirements and duration of treatment for preterm and low birthweight infants remain uncertain[6-9]. Two liquid vitamin D supplements are currently available in NZ ensure the correct formulation is chosen based on indication. **Colecalciferol (Clinicians® Vitamin D drops)** – for prevention of vitamin D deficiency due to prematurity, lack of sufficient sunlight and/or malabsorption due to conditions such as biliary obstruction, coeliac disease, cyctic fibrosis or short gut. **Alfacalcidiol (One-Alfa® drops)** – for treatment of severe resistant forms of vitamin D deficiency, disorders of synthesis of biologically active forms of vitamin D such as chronic liver or kidney disease, induction of excessive metabolism of vitamin D by enzyme inducers such as anticonvulsants or management of other Vitamin D sensitive endocrine disorders such as hypoparathyroidism or secondary hyperparathyroidism.

References	1. https://puria.co.nz/vitamin-d-drops/ 2. www.nzfc.org.nz 3. www.uptodate.com 4. Lacy et al. Drug Information Handbook 2016 Lexicomp INC.p 5. Koletzko B, Poindexter B, Uauy R. Recommended Nutrient Intake Levels for Stable, Fully Enterally Fed Very Low Birth Weight Infants. In: Koletzko B, Poindexter B, Uauy R, editors. Nutritional Care of Preterm Infants Scientific Basis and Practical Guidelines. Basel Karger; 2014. p. 297-9. 6. Cho SY, Park HK, Lee HJ: Efficacy and safety of early supplementation with 800 IU of vitamin D in very preterm infants followed by underlying levels of vitamin D at birth. Ital J Pediatr 2017, 43(1):45. 7. Natarajan CK, Sankar MJ, Agarwal R, Pratap OT, Jain V, Gupta N, Gupta AK, Deorari AK, Paul VK, Sreenivas V: Trial of daily vitamin D supplementation in preterm infants. Pediatrics 2014, 133(3):e628-634. 8. Anderson-Berry A, Thoene M, Wagner J, Lyden E, Jones G, Kaufmann M, Van Ormer M, Hanson C: Randomized trial of two doses of vitamin D3 in preterm infants <32 weeks: Dose impact on achieving desired serum 25(OH)D3 in a NICU population. PloS ONE 2017, 12(10):e0185950. 9. Fort P, Salas AA, Nicola T, Craig CM, Carlo WA, Ambalavanan N: A Comparison of 3 Vitamin D Dosing Regimens in Extremely Preterm Infants: A Randomized Controlled Trial. J Pediatr 2016, 174:132-138 e131.
Updated by	N Austin, B Robertshawe, B Cormack(ADHB dietitian),April 2019 Clarification around Vit D levels and indications for alfacalcidiol Oct 2020 N Austin, A Lynn, M Wallenstein July 2021 (revise dosing and levels) A Lynn, N Austin (audit of levels <28 weekers, March 2022) A Lynn, B Robertshawe (amend cholestasis dose to be in alignment with Starship) 2023
Consensus	April 2019 (Commenced for national use, local changes made 2021, 2022)