# Vitamins in cholestasis

## Newborn use only

**2025**

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| **Alert** | The dose recommendations for cholestasis are based on expert opinion.<br>International units (IU) are labelled as units in this formulary.<br>Biological Therapies Vitamin A oral solution and OsteVit D oral liquid contains sodium benzoate. Avoid exposure of >99mg/kg/day in neonates. |
| **Indication** | Neonatal cholestasis |
| **Action** | Vitamin A: Fat soluble vitamin required for vision, growth and bone development, immune function and maintenance of epithelial cells particularly in the retina and respiratory tract tissues.<br>Vitamin D: Regulating levels of calcium and phosphorus and mineralisation of bone.<br>Vitamin E: Antioxidant protecting cell membranes from oxidative stress. Active isomer is α-tocopherol.<br>Vitamin K: Promotes the activation of blood coagulation Factors II, VII, IX and X in the liver. |
| **Drug type** | Fat and water soluble vitamins |
| **Trade name** | Pentavite Infant liquid 0-3 years<br>Brauer Baby Multivitamin Liquid<br>Biological Therapies Vitamin A oral solution or Kirkman Mycelized Vitamin A drops<br>Ostelin Vitamin-D3 1000 IU liquid<br>Pretorius Micel-E oral liquid<br>Konakion MM Paediatric |
| **Presentation** | Pentavite Infant – Each 0.45 mL contains 1287 units of vitamin A and 400 units of vitamin D.<br>Brauer Baby Multivitamin Liquid – 1 mL contains 356, 200 and 6 units of vitamin A, D and E.<br>Biological Therapies Vitamin A oral solution – 0.1 mL contains 2500 units of vitamin A.<br>Kirkman Mycelized Vitamin A drops - 0.05 mL contains 5025 units vitamin A.<br>Ostelin Vitamin -D (Vitamin D3) oral liquid – 0.5 mL contains 1000 units of vitamin D.<br>Pretorius Micel-E oral liquid – 0.1 mL contains 15.6 units of vitamin E (equivalent to 10.47 mg)<br>Konakion MM Paediatric – 0.2 mL contains 2 mg vitamin $K_1$. |
| **Dose** | **Suggested starting regimen[1-4]** |

| | **Vitamin A** | **Vitamin D** | **Vitamin E** | **Vitamin $K_1$** |
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| **Dose range per day (not per kg)** | 3000-5000 units | 1000-2000 units (25-50 µg) | 15-30 units | 2 mg twice a week up to 2 mg daily |

| **Medical officers to prescribe the following combination of products** | | **Daily Dose Range** | | | |
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| **Vitamins** | **Oral preparation**<br><br>**Dose (mL) and Frequency** | **Vitamin A (units)** | **Vitamin D (units)** | **Vitamin E (units)** | **Vitamin $K_1$ (mg)** |
| Pentavite Infant | 0.45 mL once or twice daily | 1287-2574 | 400-800 (10-20 µg) | - | - |
| Brauer Baby Multivitamin Liquid- **If pentavite is not available** | 1 mL once or twice daily | 356-712 | 200-400 | 6-12 | |
| Vitamin A<br>Biological Therapies vitamin A<br>**OR**<br>Kirkman Mycelized solution | 0.1 mL daily*<br><br>**OR**<br>0.05 mL 48 hourly | 2500 | - | - | - |
| Ostelin Vitamin-D oral liquid 1000 units/0.5 mL[#] | 0.5 mL daily* | - | 1000 (25 µg) | - | - |

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| Pretorius Micel-E liquid | 0.1-0.2 mL daily* | | - | - | 15.6-31.2 | - |
| Konakion MM Paediatric | 0.2 mL twice a week to daily | | - | - | - | 2 mg twice a week to 2 mg daily |
| | | Total | 3787-5074 | 1400-1800 (35-45 µg) | 15.6-31.2 | 2 mg twice a week to 2 mg daily |

*The daily dose may be administered in two divided doses.
#Ostelin Vitamin-D is the preferred liquid because it doesn't contain sodium benzoate. Please check the strengths in each preparation before prescribing.

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| **Dose adjustment** | Not applicable |
| **Maximum dose** | |
| **Total cumulative dose** | |
| **Route** | Oral or intra-gastric tube. |
| **Preparation** | No preparation is required |
| **Administration** | Administer undiluted or mixed with a small amount of milk into infant's mouth through a feeding teat or via intra-gastric tube. |
| **Monitoring** | Check serum levels of vitamins A, D, E and PT/INR in 1-3 monthly. May need more frequent monitoring in the initial weeks of therapy. |
| **Contraindications** | Hypersensitivity to vitamin A, D, E, K or any component of the formulations.<br>Hypervitaminosis of A, E and/or D. |
| **Precautions** | Direct administration into the mouth may cause choking and apnoea. |
| **Drug interactions** | May increase effects of anticoagulant and antiplatelet agents |
| **Adverse reactions** | Hypervitaminosis A: Irritability, lethargy, vomiting, bulging fontanelle.<br>Hypervitaminosis D: Hypercalcaemia, nephrocalcinosis.<br>Vitamin E: Potentiation of coagulopathy, sepsis, necrotising enterocolitis. |
| **Overdose** | AUSTRALIA: Contact the Poisons Information Centre on 13 11 26 for information on the management of overdose<br>NEW ZEALAND: Contact the National Poisons Centre on 0800 764 766 for information on the management of overdose. |
| **Compatibility** | Not applicable |
| **Incompatibility** | Not applicable |
| **Stability** | Refer to individual product information. |
| **Storage** | All products: Store below 25°C. Protect from light.<br>Pentavite Infant liquid: Refrigerate after opening. |
| **Excipients** | Pentavite Infant liquid: sodium saccharin, pineapple flavour.<br>Brauer Baby Multivitamin Liquid: Ascorbyl palmitate, dl-alpha-tocopherol, gelatin, glycerol, maize oil, maize starch, potassium sorbate, purified water, sucrose, vegetable oil, xanthan gum.<br>Biological Therapies Vitamin A oral solution: Citric acid monohydrate, dl-alpha-tocopherol (vitamin E), glycerol, Polyethylene glycol-35, castor oil, purified water, sodium benzoate. Avoid exposure to sodium benzoate of >99 mg/kg/day in neonates.<br>Kirkman Mycelized Vitamin A drops – Purified water, castor bean oil, glycerine, citric acid, vitamin E (<1%), potassium sorbate.<br>OsteVit-D oral liquid: sodium benzoate, caramel flavour.<br>Pretorius Micel-E oral liquid: Potassium sorbate and soy bean products.<br>Konakion MM Paediatric: Glycocholic acid, lecithin, sodium hydroxide, hydrochloric acid. |
| **Special comments** | Vitamin E 1 unit = 0.67 mg α-tocopherol.<br>1 mg of retinyl palmitate = 1818 units of vitamin A. |

**Evidence**

**Background**

There is a high prevalence of vitamin deficiency in neonatal cholestasis, with one study reporting rates of deficiency for vitamin E (71%), vitamin D (61%), vitamin A (29%) and vitamin K (13%).[3] Fat-soluble vitamin serum levels should be monitored frequently in all cholestatic infants to avoid life threatening bleeding (vitamin K deficiency), bone fractures and rickets (vitamin D deficiency), corneal/retinal defects and blindness (vitamin A deficiency), and neurologic and muscular abnormalities (vitamin E deficiency).[5]

**Efficacy**

Dosing recommendations for vitamins in neonatal cholestasis vary and are based on expert opinion.[1-4] Many infants will require individual supplementation of vitamins D, A, E, or K, along with the preferred multivitamin formulation.[5]

Dosing recommendations for fat soluble vitamins are as follows:

| Author | Vitamin A | Vitamin D | Vitamin E | Vitamin K |
|---|---|---|---|---|
| Feldman[4] | 3000-10000 U/day | 800-5000 IU/day OR 1,25 $OH_2$ D3: 0.05-0.2 µg/kg/day | Maintain serum targets. No dose recommendations. | 2.5- 5 mg twice a week to every day |
| Italian society[1] | 5000-25000 IU/day | 800-5000 U/day | 15-25 U/kg/day | 2.5-5 mg twice a week to every day |
| King's college, London[3] | 1333-5000 IU/day | 1000-3000 IU/day | 15-150 U/kg/day | 1 mg/day |
| Lane et al.[2] | 5000-50000 IU/day | 1000-8000 IU/day | 1 unit/kg/day | ORAL:2.5-5 mg IM/SQ/IV: 1-10 mg/dose |

Optimal approach would be to adjust the doses based on target serum levels. Refer to practice points.

**Safety**

Excessive doses of vitamins can lead to adverse effects listed in adverse reactions.[1]

**Practice points**

Aim to maintain the normal range of serum vitamin A, E and D levels. Reference values may vary. Check with your local laboratory.

Published recommendations of INR ≤1.2 is often not possible in practice despite high doses of vitamin K. Higher INR values are often accepted as long as there is no clinical evidence of coagulation dysfunction.

**References**


1. Dani C, Pratesi S, Raimondi F, Romagnoli C. Italian guidelines for the management and treatment of neonatal cholestasis. Italian Journal of Pediatrics. 2015;41:1-12.
2. Lane E, Murray KF. Neonatal cholestasis. Pediatric Clinics. 2017;64:621-39.
3. Mancell S, Islam M, Dhawan A, Whelan K. Fat-soluble vitamin assessment, deficiency and supplementation in infants with cholestasis. Journal of Human Nutrition and Dietetics. 2022;35:273-9.
4. Feldman AG, Sokol RJ. Neonatal cholestasis. Neoreviews. 2013;14(2):e63-e73.
5. Feldman AG, Sokol RJ. Neonatal Cholestasis: Updates on Diagnostics, Therapeutics, and Prevention. NeoReviews. 2021;22:e819-e36.


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**Authors Contribution of the current version**

| | |
|---|---|
| Author/s | Srinivas Bolisetty, Nilkant Phad |
| Evidence Review | Srinivas Bolisetty |
| Expert review of the original | Kate Dehlsen, Scott Nightingale, Michael Stormon, Usha Krishnan, Lizsa Tan, Katie Marks, Andrea Horvath |
| Nursing Review | Eszter Jozsa, Bryony Malloy |

| | |
|---|---|
| Pharmacy Review | Mohammad Irfan Azeem, Thao Tran |
| ANMF Group contributors | Nilkant Phad, Bhavesh Mehta, Jutta van den Boom, Rebecca Barzegar, Amber Seigel, Kerrie Knox, Rebecca O'Grady, Cindy Chen, Michelle Jenkins, Susannah Brew, Benjamin Emerson-Parker, Renae Gengaroli, Emma Roylance, Bryony Malloy, Samantha Hassall, Dianne Lee, Trong Tran, Gloria Yoo, Charles Tian, Emma Watson |
| Final editing | Srinivas Bolisetty |
| Electronic version | Thao Tran, Cindy Chen, Helen Huynh, Ian Callander |
| Facilitator | Srinivas Bolisetty |

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