

<b>Alert</b>	The dose recommendations for cholestasis are based on expert opinion. International units (IU) are labelled as units in this formulary. Biological Therapies Vitamin A oral solution and OsteVit D oral liquid contains sodium benzoate. Avoid exposure of >99mg/kg/day in neonates.																																														
<b>Indication</b>	Neonatal cholestasis																																														
<b>Action</b>	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. Vitamin D: Regulating levels of calcium and phosphorus and mineralisation of bone. Vitamin E: Antioxidant protecting cell membranes from oxidative stress. Active isomer is $\alpha$ -tocopherol. Vitamin K: Promotes the activation of blood coagulation Factors II, VII, IX and X in the liver.																																														
<b>Drug type</b>	Fat and water soluble vitamins																																														
<b>Trade name</b>	Pentavite Infant liquid 0-3 years Brauer Baby Multivitamin Liquid Biological Therapies Vitamin A oral solution or Kirkman Mycelized Vitamin A drops Ostelin Vitamin-D3 1000 IU liquid Pretorius Micel-E oral liquid Konakion MM Paediatric																																														
<b>Presentation</b>	Pentavite Infant – Each 0.45 mL contains 1287 units of vitamin A and 400 units of vitamin D. Brauer Baby Multivitamin Liquid – 1 mL contains 356, 200 and 6 units of vitamin A, D and E. Biological Therapies Vitamin A oral solution – 0.1 mL contains 2500 units of vitamin A. Kirkman Mycelized Vitamin A drops - 0.05 mL contains 5025 units vitamin A. Ostelin Vitamin D (Vitamin D3) oral liquid – 0.5 mL contains 1000 units of vitamin D. Pretorius Micel-E oral liquid – 0.1 mL contains 15.6 units of vitamin E (equivalent to 10.47 mg) Konakion MM Paediatric – 0.2 mL contains 2 mg vitamin K <sub>1</sub> .																																														
<b>Dose</b>	<p><b>Suggested starting regimen<sup>(1-4)</sup></b></p> <table border="1"> <thead> <tr> <th></th> <th>Vitamin A</th> <th>Vitamin D</th> <th>Vitamin E</th> <th>Vitamin K<sub>1</sub></th> </tr> </thead> <tbody> <tr> <td><b>Dose range per day (not per kg)</b></td> <td>3000-5000 units</td> <td>1000-2000 units (25-50 <math>\mu</math>g)</td> <td>15-30 units</td> <td>2 mg twice a week up to 2 mg daily</td> </tr> </tbody> </table> <table border="1"> <thead> <tr> <th colspan="2">Medical officers to prescribe the following combination of products</th> <th colspan="4">Daily Dose Range</th> </tr> <tr> <th>Vitamins</th> <th>Oral preparation</th> <th>Vitamin A (units)</th> <th>Vitamin D (units)</th> <th>Vitamin E (units)</th> <th>Vitamin K<sub>1</sub> (mg)</th> </tr> </thead> <tbody> <tr> <td>Pentavite Infant</td> <td>0.45 mL once or twice daily</td> <td>1287-2574</td> <td>400-800 (10-20 <math>\mu</math>g)</td> <td>-</td> <td>-</td> </tr> <tr> <td>Brauer Baby Multivitamin Liquid- <b>If pentavite is not available</b></td> <td>1 mL once or twice daily</td> <td>356-712</td> <td>200-400</td> <td>6-12</td> <td></td> </tr> <tr> <td><u>Vitamin A</u> Biological Therapies vitamin A <b>OR</b> Kirkman Mycelized solution</td> <td>0.1 mL daily* <b>OR</b> 0.05 mL 48 hourly</td> <td>2500</td> <td>-</td> <td>-</td> <td>-</td> </tr> <tr> <td>Ostelin Vitamin-D oral liquid 1000 units/0.5 mL<sup>#</sup></td> <td>0.5 mL daily*</td> <td>-</td> <td>1000 (25 <math>\mu</math>g)</td> <td>-</td> <td>-</td> </tr> </tbody> </table>		Vitamin A	Vitamin D	Vitamin E	Vitamin K <sub>1</sub>	<b>Dose range per day (not per kg)</b>	3000-5000 units	1000-2000 units (25-50 $\mu$ g)	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				Vitamins	Oral preparation	Vitamin A (units)	Vitamin D (units)	Vitamin E (units)	Vitamin K <sub>1</sub> (mg)	Pentavite Infant	0.45 mL once or twice daily	1287-2574	400-800 (10-20 $\mu$ g)	-	-	Brauer Baby Multivitamin Liquid- <b>If pentavite is not available</b>	1 mL once or twice daily	356-712	200-400	6-12		<u>Vitamin A</u> Biological Therapies vitamin A <b>OR</b> Kirkman Mycelized solution	0.1 mL daily* <b>OR</b> 0.05 mL 48 hourly	2500	-	-	-	Ostelin Vitamin-D oral liquid 1000 units/0.5 mL <sup>#</sup>	0.5 mL daily*	-	1000 (25 $\mu$ g)	-	-
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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

\*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.

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

<b>Evidence</b>	<b>Background</b>																												
	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%). <sup>(3)</sup> 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). <sup>(5)</sup>																												
	<b>Efficacy</b>																												
	Dosing recommendations for vitamins in neonatal cholestasis vary and are based on expert opinion. <sup>(1-4)</sup> Many infants will require individual supplementation of vitamins D, A, E, or K, along with the preferred multivitamin formulation. <sup>(5)</sup>																												
	Dosing recommendations for fat soluble vitamins are as follows:																												
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Optimal approach would be to adjust the doses based on target serum levels. Refer to practice points.																													
<b>Safety</b>																													
Excessive doses of vitamins can lead to adverse effects listed in adverse reactions. <sup>(1)</sup>																													
<b>Practice points</b>	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.																												
<b>References</b>	<ol style="list-style-type: none"> <li>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.</li> <li>2. Lane E, Murray KF. Neonatal cholestasis. Pediatric Clinics. 2017;64:621-39.</li> <li>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.</li> <li>4. Feldman AG, Sokol RJ. Neonatal cholestasis. Neoreviews. 2013;14(2):e63-e73.</li> <li>5. Feldman AG, Sokol RJ. Neonatal Cholestasis: Updates on Diagnostics, Therapeutics, and Prevention. NeoReviews. 2021;22:e819-e36.</li> </ol>																												

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