



URSODEOXYCHOLIC ACID

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Formulary: Restricted Requires Neonatologist or relevant specialist review within 24 hours.	
Presentation	Oral Suspension: 50 mg/mL
Drug Class	Gastrointestinal Medication
Indication	Treatment of neonatal cholestasis associated with parenteral nutrition, biliary atresia and cystic fibrosis
Special Considerations	Hypersensitivity to ursodeoxycholic acid Complete biliary obstruction
Monitoring	Liver function tests and serum bilirubin concentration Observe stool colour
Interactions	Antacids which contain aluminium bind to ursodeoxycholic acid and reduces its absorption.
Side Effects	Common: Nausea, vomiting, constipation, flatulence
	Infrequent: Transient increase in liver function test values
	Rare: Transient hypercholesterolaemia
Storage & Stability	Oral Suspension: Store below 25°C <ul style="list-style-type: none"> • Write date opened on bottle. • Discard suspension 4 months after opening.
Comments	<ul style="list-style-type: none"> • Consider fat soluble vitamin supplementation if required to prevent fat-soluble vitamin deficiency during cholestasis. • Contact pharmacy if commercial prepared oral suspension is not available due to supplier issues – compounding by pharmacy may be possible.

ORAL	Presentation	Oral Suspension: 50 mg/mL	
	Dosage	Neonatal Cholestasis 10 to 15 mg/kg every 12 hours <ul style="list-style-type: none"> • Dose adjustment <ul style="list-style-type: none"> • Renal and/or hepatic impairment: No adjustments provided by manufacturer's labelling. 	
	Administration	<ul style="list-style-type: none"> • Shake well before use • Draw prescribed dose into oral/enteral syringe • Can be given Oral/OGT/NGT • May be given anytime in relation to feeds 	

Related Policies, Procedures, and Guidelines

HDWA Mandatory Policies: N/A

Clinical Practice Guidelines: N/A

WNHS Pharmaceutical and Medicines Management Guidelines: N/A

References

Australian Medicines Handbook. Ursodeoxycholic Acid. In: Australian Medicines Handbook [Internet]. Adelaide (South Australia): Australian Medicines Handbook; 2024 [cited 2024 Feb 9]. Available from: <https://amhonline.amh.net.au/>

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Document history

Keywords	Ursodeoxycholic Acid, Ursodiol, Ursofalk, Cholestasis				
Document Owner:	Chief Pharmacist				
Author/ Reviewer	KEMH & PCH Pharmacy/Neonatology Directorate				
Version Info:	4.0 – full review, new template				
Date First Issued:	31/01/2001	Last Reviewed:	09/02/2024	Review Date:	09/02/2029
Endorsed by:	Neonatal Directorate Management Group			Date:	27/02/2024
NSQHS Standards Applicable:	<input checked="" type="checkbox"/>  Std 1: Clinical Governance		<input checked="" type="checkbox"/>  Std 4: Medication Safety		
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