

Alert	
Indication	<p>1) Preterm neonates < 32 weeks gestation or < 1800 g birth weight: For prevention of necrotising enterocolitis (NEC), late-onset sepsis, mortality and reduction in time to reach full feeds.[1-3]</p> <p>2) Small for gestational age, preterm neonates with abnormal umbilical artery Doppler for prevention of NEC and reduction in time to reach full feeds. [1, 4]</p> <p>3) The safety and efficacy for other populations of infants at risk of NEC, sepsis or feed intolerance including infants with asphyxia, undergoing exchange transfusion, abdominal surgical conditions and congenital heart disease has not been assessed in clinical studies.</p>
Action	Probiotics promote colonisation of the gut with beneficial organisms, preventing colonisation by pathogens, improving the maturity and function of gut mucosal barrier, and modulating the immune system (e.g. TLR4 receptor, nuclear factor-kB and inflammatory cytokines) to the advantage of the host. [5]
Drug Type	Probiotic bacteria
Trade Name	Infloran
Presentation	250 mg capsule containing <i>Lactobacillus acidophilus</i> [10 ⁹ colony-forming units, NCDO 1748; National Collection of Dairy Organisms] and <i>Bifidobacterium bifidum</i> [10 ⁹ colony-forming units, NCDO 1453; National Collection of Dairy Organisms, Reading, United Kingdom]; Laboratorio Farmaceutico, Italy. [6, 7]
Dosage/Interval	<p>Commence the dose soon after birth irrespective of the feeds.</p> <p>Birthweight < 1 kg: Commence with ½ capsule (125 mg) daily until neonate is on 40 mL/kg/day of oral feeds and then change to 1 capsule daily until 34–36 weeks or considered no longer at risk of NEC.</p> <p>Birthweight ≥ 1 kg: Commence 1 capsule (250 mg) daily and continue until 34–36 weeks or considered no longer at risk of NEC.</p>
Maximum daily dose	2 capsules (500 mg) daily
Route	Oral/Orogastric
Preparation/Dilution	The contents of ONE capsule should be dissolved in 2 mL of mother’s EBM/donor human milk/water for injection/formula. Draw up required volume (1 mL for 125 mg and 2 mL for 250 mg)
Administration	Oral: Administer with feeds if possible.
Monitoring	
Contraindications	No known contraindications.
Precautions	Administration of the probiotics may be discontinued during periods when the integrity of the gut mucosa is considered compromised. The common scenarios include intestinal perforation, severe sepsis, critical illness, bile aspirates, NEC and surgical gut anomalies.[8] No efficacy or safety data available on use of probiotics in infants after definite NEC.
Drug Interactions	None reported.
Adverse Reactions	<p>Rare.</p> <p>Probiotic sepsis has been reported in preterm neonates with surgical conditions, immune suppression and when gut barrier is compromised. [8]</p>
Stability	<i>Bifidobacterium bifidum</i> is particularly heat sensitive, so once the capsule is open it should be used immediately.
Storage	Store at 2–8°C.
Special Comments	<p>Please note: There are 2 Infloran preparations. (1) Infloran and (2) Infloran infantis. Infloran infantis is not available in Australia.</p> <p>Infloran contains <i>Bifidobacterium bifidum</i> and <i>Lactobacillus acidophilus</i>.</p> <p>Infloran infantis contains <i>Bifidobacterium infantis</i> and <i>Lactobacillus acidophilus</i>.</p> <p>Median 2 to 3 x 10⁹ CFU dose has been shown to prevent NEC.[7] There is no known benefit in terms of prevention of NEC with doses higher than 3 x 10⁹ CFU. One capsule of</p>

	<p>Infloran should provide minimum of 2×10^9 CFU. Studies have shown that up to 2 capsules/day dose is well tolerated by older premature neonates (> 1500 g).[8]</p> <p>All probiotic preparations given to newborn infants should have undergone quality testing in an Australian TGA equivalent regulated system including batch to batch testing for colony count to rule out contamination.[8]</p> <p>The intestinal barrier could be compromised during severe sepsis and critical illness. Probiotics may be discontinued in the initial stages of severe late onset sepsis, suspected NEC, or critical illness.[8]</p>
Evidence summary	Refer to full version.
References	Refer to full version.

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