Bifidobacterium breve M-16V

Newborn use only

2020

Alert	Unregistered product in Australia. Must be prescribed by TGA Special Access Scheme or via Authorised Prescriber Pathway, after obtaining parental consent. *Bifidobacterium breve M-16V* (*B. breve M-16V*) has not yet been shown in RCTs to reduce NEC or sepsis. 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 have not been assessed in clinical studies.
Indication	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] 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]
Action	Promotes 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 to the advantage of the host. [5]
Drug type	Probiotic bacteria
Trade name	Morinaga Bifidus M-16V
Presentation	1.0–1.2 g powder per sachet containing more than 1 billion *B. breve M-16V* per sachet at the end of shelf life.[6]
Dose	½ sachet twice a day to commence soon after birth irrespective of the feeds and continue until discharge [14] or considered no longer at risk of NEC.
Dose adjustment	Therapeutic hypothermia – Not applicable. ECMO – Not applicable. Renal impairment – No information. Hepatic impairment – No information.
Maximum dose	1 sachet
Total cumulative dose	
Route	Oral Intragastric
Preparation	Dissolve ONE sachet in 2 mL of mother's EBM/donor human milk/water for injection/formula. Draw up required volume (1 mL for ½ sachet and 2 mL for 1 sachet).
Administration	Oral: Administer prescribed amount with or without food. Discard unused portion.
Monitoring	Not applicable.
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.[7] No efficacy or safety data available on use of probiotics in infants after definite NEC.
Drug interactions	None reported.
Adverse reactions	Rare. Probiotic sepsis has been reported in preterm neonates with surgical conditions, immune suppression and when gut barrier is compromised. [7].
Compatibility	No data available/ not applicable
Incompatibility	No data available/ not applicable
Stability	*Bifidobacterium breve* M-16V is p*P*articularly heat sensitive, so once the sachet is open it should be used immediately.
Storage	Store at room temperature.
Excipients	
Special comments	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.[7]
Evidence	Refer to full version.
Practice points	Refer to full version.
References	Refer to full version.

VERSION/NUMBER	DATE
Original 1.0	**2/11/2017**

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