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* has not yet been shown in RCTs to reduce NEC or sepsis.

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]
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 have not been assessed in clinical studies.

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 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 (stick) containing more than 1 billion *B. breve* M-16V per sachet at the end of shelf life.[6]

Dosage/Interval

Commence ½ sachet BD soon after birth irrespective of the feeds and continue until discharge [14] or considered no longer at risk of NEC.

Maximum daily dose

1 sachet

Route

Oral/Orogastric

Preparation/Dilution

The contents of ONE sachet should be dissolved 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 with or without food. Discard unused portion.

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].

Stability

*Bifidobacterium breve* M-16V is particularly heat sensitive, so once the sachet is open it should be used immediately.

Storage

Store at room temperature.

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 summary

Probiotics

Several systematic reviews and randomised, controlled trials have shown that enteral probiotics significantly reduce the risk of NEC (≥ stage II), late-onset sepsis, all-cause mortality and time to full enteral feeds. [1-3] (LOE 1, GOR A) Multiple strains of probiotics may be more effective in preventing NEC and mortality than single strains. [8] (LOE I, GOR B)

Probiotics for prevention of NEC in preterm infants: Enteral probiotic supplementation significantly reduced the incidence of severe NEC (RR 0.43, 95% CI 0.33 to 0.56; 20
**Bifidobacterium breve M-16V**

Newborn Use Only

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**Efficacy:** In a comparative study with historical controls, *B. breve M-16V* was associated with a reduced incidence of NEC, sepsis and mortality from sepsis. (LOE III-3 GOR C) [14].

A before and after retrospective study showed that *B. breve M-16V* was associated with decreased NEC ≥ Stage II and NEC ≥ Stage II or all-cause mortality in neonates < 34 weeks [20]. *B. breve M-16V* has not yet been shown in RCTs to reduce NEC or sepsis.

**Safety:** No adverse effects, particularly probiotic-induced sepsis, were reported in any of the studies using *B. breve M-16V* in term and preterm neonates. [16-22]

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**References**


Original version Date: 2/11/2017  
Author: NMF Consensus Group  
Current Version number:  1.0  
Current Version Date:  2/11/2017  
Risk Rating: Medium  
Due for Review:  2/11/2020  
Approval by: As per Local policy  
Approval Date:  2/11/2020  

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