### Bifidobacterium breve M-16V

**Newborn Use Only**

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**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.

**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**

Refer to full version.

**References**

Refer to full version.

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