



Consent for probiotic supplementation for premature babies

Please note that consent for probiotic *Bifidobacterium breve* M16V supplementation is voluntary and subjects can withdraw at any time with no impact on current or future care.

I have read
Given Names Surname

the information explaining Probiotic *Bifidobacterium breve* M16V supplementation that is to be given to my baby

I have read and understood the information given to me. Any questions I have asked have been answered to my satisfaction. I understand that

- (1) This probiotic product is not approved for marketing in Australia but its use has been approved under the provisions of section 19(5) or section 41 HC of the *Therapeutic Goods Act 1989*
- (2) I understand that the Commonwealth can give no guarantee as to the quality, safety, and efficacy of this product probiotic bifidobacterium breve M16 V.
- (3) Treatment with this probiotic has been shown to reduce the risk of NEC in premature babies.
- (4) Based on current knowledge there are no other known risks and side effects of this probiotic.
- (5) It is possible that there could be unknown risks and late side effects.
- (6) There are currently no alternative treatments using approved products that are available.

I confirm that the above statements have been explained to me and in this knowledge agree to administration of the product probiotic *Bifidobacterium breve* M16V to my baby.

Dated day of 20

Signature

I, have explained the above to the signatory who stated that he/she understood the same.

Signature

Date.....



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Probiotic (Bifidobacteria breve M16 V) supplementation for reducing the risk of necrotizing enterocolitis in premature babies

Parent Information sheet

We sincerely appreciate your efforts during this stressful time in reading this information. Please take your own time, and ask any questions that you may have, before deciding whether your baby could receive a probiotic supplement.

Probiotics are live beneficial microorganisms that are naturally present in the digestive tract. They promote health by suppressing the growth of potentially harmful bacteria, improving immune function, and enhancing the protective barrier of the digestive tract. Human beings have been consuming these bacteria for hundreds of years in the form of various food supplements, the commonest being “Yakult” (containing the bacteria lactobacillus acidophilus).

Immature bowel function in premature babies can cause feeding difficulties, and necrotising enterocolitis (NEC) - a potentially disastrous inflammatory condition of the bowel which can result in need for surgery or even death. These conditions also delay the time to tolerate full milk feeds and consequently increase hospital stay.

Cumulative evidence from 56 clinical trials around the world involving more than 10,000 premature babies (Birth weight under 1500 g and gestation under 33 weeks) suggests that probiotic supplements reduce the risk of NEC and death significantly in this population.

Our team has independently assessed a probiotic product (Bifidobacterium breve M16) manufactured by Morinaga Industries, Japan. This product has been shown to reduce the risk of NEC and infections in premature babies in 2 previous studies. The quality and sterility of this product has proved to be satisfactory. We have not observed any complications of the supplementation with this probiotic in our trial in 120 premature babies. Based on the results of this trial, we introduced this probiotic for routine use in premature babies in June 2012. Considering that the risk of feeding difficulties and NEC is high in your baby, we wish to provide him/her this probiotic supplementation in his/her best interest.

Are there any side effects, risks of the probiotic supplement?

Infection from the “probiotic” bacteria is an uncommon but a possible adverse effect that has been reported by researchers. However it is important to note that none of the clinical trials in premature babies to date have reported any significant side effects of probiotic supplements including probiotic infection. Probiotic infections are also easier to treat compared with those from highly toxic organisms. We will be monitoring your baby carefully for this possibility and treat her promptly with appropriate antibiotics if necessary.

As per the guidelines of the national regulatory agency we are also required to let you know that

- (7) This probiotic product is not approved for marketing in Australia.
- (8) Treatment with this probiotic has been shown to reduce the risk of NEC, and infections in premature babies.
- (9) To our knowledge there are no other known risks and side effects of this probiotic.
- (10) It is possible that there could be unknown risks and late side effects.
- (11) There are currently no alternative treatments using approved products that are available.

Please contact the consultant neonatologist looking after your baby or contact us to provide you with more information if needed.



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