



Probiotic Supplementation to reduce the risk of Necrotising Enterocolitis in premature babies

Dear Parent(s)/Guardians,

We appreciate your efforts during this stressful time in reading this information. Please take your time, and clarify your queries, before deciding whether your baby could receive a probiotic supplement.

Premature babies are at risk of developing a serious condition of the intestines called necrotising enterocolitis (NEC). It can lead to major damage to the intestines and some will need surgery to remove part or whole of the unhealthy intestines. In some cases, NEC can lead to death. Surviving infants are at risk of disability in the future. Hence, it is important to prevent NEC from occurring in the first place.

Probiotics (healthy bacteria) have been shown to reduce the risk of developing NEC and other serious infections in premature infants and improve their feeding tolerance. Probiotics achieve these beneficial effects by suppressing the growth of harmful bacteria in the gut and strengthening the immune system of premature babies.

We have been using a probiotic product called *B. breve* M-16V (Morinaga Milk Industries, Japan) since 2011. Our experience is that this product is very safe and beneficial for premature babies. Recent evidence suggests that probiotic mixtures that have more than one strain (type) of the healthy bacteria may provide more benefits than those containing only one strain. Therefore, we have introduced a three-strain probiotic product from the same Japanese company (Triple Bifidus: *B. breve* M-16V, *B. infantis* M-63 and *B. longum* BB536) for use in premature babies (born at less than 35 weeks) in the neonatal units at King Edward Memorial Hospital and Perth Children's Hospital. We have tested this product in a scientific study and found it to be safe and effective in premature babies.

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

Being live bacteria, the probiotic bacteria may themselves cause an infection, but it is extremely rare. We have given probiotics to more than 2000 premature babies since 2011 to December 2022. None of those babies had developed infection due to the probiotic bacteria. Even then, your baby will be monitored for any risk of probiotic infection and treated with antibiotics if it occurs.

As per the guidelines of the National Regulatory Agency, we are also required to let you know the following:

1. This probiotic product is not approved for marketing in Australia
2. Probiotic supplementation has been shown to reduce the risk of NEC and infections in premature babies
3. To our knowledge there are no other known risks and side effects of this probiotic
4. It is possible that there could be unknown risks and late side effects

We hope this information is adequate for you to decide. Please contact the consultant neonatologist looking after your baby or contact us to provide you with more information if needed. Thanks for your assistance.

Regards,

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Consent for Probiotic Supplementation to reduce the risk of Necrotising Enterocolitis in premature babies

Please note that consent for probiotic supplementation using the 'Triple Bifidus' product is voluntary, and subjects can withdraw at any time with no impact on current or future care.

I

(Given Name) (Surname)

Have read the information explaining Probiotic 'Triple Bifidus' supplementation that is to be given to my baby (name):

.....

I have read and understood the information given to me. All 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. The Commonwealth can give no guarantee as to the quality, safety and efficacy of this three-strain bifidobacteria probiotic (triple Bifidus).
3. Treatment with probiotics has been shown to reduce the risk of NEC in premature babies
4. Based on current knowledge, there are no known risks and side effects of this probiotic.
5. It is possible that there could be unknown risks and late side effects

I confirm that the above statements have been explained to me and in this knowledge agree to administration of the probiotic 'Triple Bifidus' to my baby.

Dated:..... (day) of(month) 20.....(year)

Signature:

.....

Staff Use:

Ihave explained the above to the signatory who stated that he/she understood the same.

Name..... Signature:

Date:.....



Government of Western Australia
Child and Adolescent Health Service

This document can be made available in alternative formats on request for a person with a disability.

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