EMR501010

PROBIOTIC SUPPLEMENTATION TO REDUCE THE RISK OF NECROTISING ENTEROCOLITIS IN PREMATURE BABIES

Dear Parent(s)/Guardians,

Premature babies less than 35 weeks are at risk of developing a serious condition of the intestines called necrotising enterocolitis (NEC) which can lead to major damage to the intestines. Some babies will need surgery to remove part of, or all of the unhealthy intestines, and in some cases, NEC can lead to death. It is therefore important to prevent NEC from occurring in the first place. In preterm babies' healthy bacteria (Probiotics) have been shown to:

- Reduce the risk of developing NEC and other serious infections
- Improve feeding tolerance by suppressing the growth of harmful bacteria in the gut
- Strengthen the immune system

We acknowledge this is a stressful time for you so please take your time to read this information and discuss your queries with us, before deciding whether your baby can receive probiotic supplements.

Since 2011 we have used a probiotic product called ***B. breve*** **M-16V** (Morinaga Milk Industries, Japan). In our experience this product is very safe and beneficial for premature babies. Recent evidence suggests that probiotic mixtures with more than one type (strain) of the healthy bacteria has more benefits than those with only one type. Therefore, we have now 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**). We have tested this product in a scientific study and found it to be safe and effective in premature babies. Your baby will also be monitored for any risk of probiotic infection and treated with antibiotics if it occurs.

Side effects and/or risks of probiotic supplements

We have given probiotics to more than 2000 premature babies since 2011 and none of these babies developed an infection due to the probiotic bacteria.

This Triple Bifidus 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. Therefore, we are required to let you know the following:

- Being live bacteria, the probiotic bacteria may themselves cause an infection, but it is extremely rare.
- It is possible that there could be unknown risks and late side effects. To our knowledge there are no known risks and side effects of this probiotic.

Please note that consent for probiotic supplementation using the 'Triple Bifidus' product is voluntary, and you can withdraw your consent at any time with no impact on current or future care. Contact the consultant neonatologist looking after your baby if you require more information.

Declaration of Health Practitioner (clinician obtaining consent to complete)

I have provided the Parent(s)/Guardian with information on probiotics and the Triple Bifidus product and I have asked if further information is required. I have explained the risks and benefits associated with Probiotics.

Full Name (print)_____ Designation_____

Signature_____ Date_____

Interpreter service used? Yes / No If Yes, specify: Telephone / On site *(please circle)*

Parent(s)/Guardian Declaration

I have read the information explaining probiotic ('*Triple Bifidus')* supplementation to be given to my baby _____ (print name)

I understand the information given to me and have had the opportunity to ask questions which have been answered to my satisfaction.

I confirm that the statements below have been explained to me and I agree to administration of the probiotic 'Triple Bifidus' mix to my baby:

- 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
- The Commonwealth can give no guarantee as to the quality, safety and efficacy of this three-strain probiotic.
- Treatment with probiotics has been shown to reduce the risk of NEC in premature babies
- Based on current knowledge, there are no known risks and side effects of this probiotic. It is possible that there could be unknown risks and late side effects

Full name (print)_____Date_____

Signature_____

For further queries please contact Dr Gayatri Jape, A/ Prof. Shripada Rao and Clinical Prof. Dr Sanjay Patole. Neonatology, Child and Adolescent Health Service. King Edward Memorial and Perth Children's Hospitals, WA 6008. Phone: (08) 6458 1260, (08) 64582222

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