Report assessing the safety of Lactobacillus Reuteri NCIMB 30351 used in BioAmicus probiotic products

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Purpose:

To test the safety of Lactobacillus Reuteri NCIMB 30351 in full term healthy infants under the age of 12 months.

Background:

50 Healthy full term infants between the ages of 3 weeks to 12 months were used in this study to determine the safety of the regular BioAmicus Reuteri liquid probiotic drops. The main active ingredient of this product is Lactobacillus Reuteri NCIMB 30351.

The concentration of this active ingredient is 200 Million Colony Forming Units (CFU) per 5 drop dose (approximately 0.2ml). The recommended dosage is once per day.

The main active ingredient is a strain of Lactobacillus reuteri, considered a safe bacterial species which naturally occurs in the breast milk of healthy mothers and passed onto their children through breast feeding. Supplementation may be useful in infants who are not breast fed or are being breast fed by mothers who lack this species of bacteria.

Method:

50 Healthy full term infants between the ages of 3 weeks to 12 months were used in this study to determine the safety of the active ingredient in regular BioAmicus Reuteri liquid probiotic drops.

The study was conducted over a period of 2 months from January to February 2015.

Each subject participant was administered 1 dose per day, for the duration of 1 week, via spoon feeding by a BioAmicus study coordinator.

Study participants fell under the following age categories at the start of the study:

3 weeks to 1 month:	2 participants
1 month to 2 months:	4 participants
2 months to 3 months:	4 participants
3 months to 4 months:	6 participants
4 months to 5 months:	7 participants
5 months to 6 months:	7 participants

6 months to 7 months:	5 participants
7 months to 8 months:	4 participants
8 months to 9 months:	1 participants
9 months to 10 months:	3 participants
10 months to 11 months:	3 participants
11 months to 12 months:	4 participants

136 GEARY AVENUE UNIT 216
TORONTO, ONTARIO
M6H 4H1 CANADA
WWW.BIOAMICUS.COM
Tel: +1 (877) 246-4769

Study participant guardians were compensated only after the completion of 7 days of continuous use and the follow up which occurred 7 days after the final dose was administered.

The criteria used to assess safety was to report any observable adverse conditions which may have developed while using the product or may have developed after discontinuing product for 1 week. This included a list of the following:

i) changes in mood such as irritability or crying
ii) changes in bowel movements such as diarrhea or constipation
iii) changes in digestion, eating habits or preferences, such as loss of appetite.
iv) development of any allergic or inflammatory reactions, such as skin rashes or hives.
v) development or increase in gas or reflux
vi) any reported negative health conditions which coincided with the use of this product.

Results:

Each of the infants was observed for a week while taking the recommended dosage.

None of them developed any reported negative side effects. See Table 1: *Reported side effects from BioAmicus Reuteri usage*

Table 1: *Reported side effects from BioAmicus Reuteri usage*

	During the 7 days of usage	7 days after the end of usage
Increased Irritability or crying	No negative side effects observed in any participant	No negative side effects observed in any participant
Diarrhea or constipation	No negative side effects observed in any participant	No negative side effects observed in any participant
changes in digestion, eating habits, preferences or appetite	No negative side effects observed in any participant	No negative side effects observed in any participant
development of any allergic or inflammatory reactions	No negative side effects observed in any participant	No negative side effects observed in any participant
development or increase in gas or reflux	No negative side effects observed in any participant	No negative side effects observed in any participant
Negative health conditions coinciding with use of this product	No negative side effects observed in any participant	No negative side effects observed in any participant

Follow up was conducted after a full week (7 days) had passed since the final administration of a dosage to check for any delayed effects. There were no reported negative health effects in any of the 50 test participants.

Discussion:

No negative side were observed over the 2 weeks involved in the study for each participant.

This study does not determine whether the active ingredient Lactobacillus Reuteri NCIMB 30351 in this product can be given to an infant who is experiencing any diagnosed health condition which requires medical attention or treatment.

It is the recommendation of BioAmicus that this product not be given to an infant suffering from vomiting, fever, bloody diarrhea or severe abdominal pain.

We recommend the consultation of a healthcare practitioner prior to usage.

Conclusion:

The strain of Lactobacillus Reuteri NCIMB 30351 used in BioAmicus Reuteri, at 200 million CFU per dose is by this initial report safe to use in healthy infants under the age of 12 months who are not experiencing any underlying medical conditions or complications.

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