INFORMED CONSENT FORM

Title of the *Clinical Study:*
Open-Label, Prospective, Multicenter Study to Assess efficacy and safety of Lactacol/Lactazak®, a food supplement in intestinal colic and bloating

Doctor: _____
Title: _____
Institution: _____
Address: _____
Phone number: _____

VOLUNTEER INFORMATION /RESEARCH DETAILS

Dear Madam/Sir, as the child's legal representative, you are invited to participate in the clinical study. Your agreement to your child's participation in the study is voluntary.
Before you decide whether you want your child to be part of this clinical, it is essential to read and understand the following information carefully.
Take as much time as you need to understand this document.
You will receive two such original documents. Please sign and date these documents and give a copy to the child's doctor for archiving. Please keep the other copy for you.

INTRODUCTION

The informed consent form describes the purpose, procedures, benefits, risks, or discomfort of this research, alternative methods, and the right to withdraw from this research at any time without affecting the relationship with the child's doctor. If you decide to stop administering the research product during the research, you must return the remaining product. We need to keep watching your child as part of the research, even if you stop administering the research product. If you do not want to continue with these procedures, we will ask for your permission to contact you until the end of the research to obtain information about the child's health status. If you decide to withdraw entirely from the research, the collected data will be kept in the database.
Participation in this research will last approximately 2 weeks.

Authorized person for informed consent form initials	Participant's initials	Witness initials (if applicable)

What does this research propose?

This research aims to assess the product efficiency and safety of Lactacol/Lactazak ® - in pediatric population 0-4 months – in reducing the baby crying due to colic during study period and reducing bloating.

Procedures

The child you legally represent is invited to participate in this research. For this, you need to sign the Informed Consent Form and participate together with the child in all of the visits included in the Data Collection Plan, providing personal, medical and demographic data. It is essential that the child doesn't have or hasn't had, any allergic reactions to one of the product's ingredients. **Lactacol/Lactazak ®** composition: Lactase (Beta-galactosidase) 700 FCC ALU, sunflower oil, Vitamin E, Lactase (Beta-galactosidase), anticaking: magnesium stearate; bamboo fiber.

If the selection criteria are met the child will be enrolled in the research, the Product will be administered for 14 consecutive days.

There will be two visits as follows:

• **Visit 1** – Screening and Enrollment visit – You will be informed about this research on this visit and receive information about research procedures. After you take enough time to sign the Informed Consent Form, the child's doctor will collect demographic data, check the child's medical history, perform the child's the physical examination, assess the concomitant diseases & medication; the doctor will perform also the evaluation of the clinical symptoms the child is experiencing and the product will be alocated.

• **Visit 2** will take place 14 days (+/- 2 days) after starting the administration of the Product. During this visit, the child's physical examination will be performed, the clinical symptoms will be reevaluated, and you will discuss the product adherence. You will also discuss with the child's doctor about eventual adverse events.

• **Visit 3 (Phone Follow-up)** will take place 28 days (+/- 5 days) after the administering of the Product. During this visit, the clinical symptoms will be reevaluated. You will also discuss with the child's doctor about eventual adverse events.

The Product will be administered according to the product leaflet. At each visit, you will have to visit the doctor together with the child.
During this research, the child should not take other similar products. If you think he needs them or have any concerns, you should contact the doctor.

SIDE EFFECTS

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During the research, the child will be monitored by his doctor and treated appropriately in any side effects. If the child experiences any side effects at home, you should immediately contact his doctor at the phone number below:
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You are encouraged to write down and tell the doctor about any changes you notice, during the Product administration.

Benefits

This Product could be beneficial for the child in relieving the symptoms he is experiencing: the baby crying due to colic and bloating.
The research Product may give him personal benefits or not do so. Even if there will be no benefits for himself, this research's results may help improve the efficiency and safety profile of the product.

The participation in this research is voluntary.

If this plan does not deliver the expected results, the child's doctor will decide whether or not to continue administering this product.

Risks and inconvenience

Lactacol/Lactazak ® is a dietary supplement based on Lactase which helps lactose digestion by reducing fermentation and gas production. There are no side effects known in **Lactacol/Lactazak ®** administration. You, as the child's legal representative, are not obliged to participate in this research, and the doctor will tell you about other solutions and their risks and benefits. The child physician will recommend the treatment strategy for him. So, the doctor may prescribe an alternative Product.

Costs and compensation for participating in this research

Participation in this research does not suppose any cost from your side.

Other considerations

The documents with information on your child participation in this research will remain confidential in accordance with the applicable regulatory requirements.
However, identifiable personal data will be made available to the staff involved in the research, the clinical monitor for the purpose of monitoring, the quality assurance auditor and the competent authorities, when necessary. Any publication of the research results will be done without mentioning any name. By signing this informed consent form, you will authorize the child doctor to hand over the medical papers attached to the research to: the monitor, the auditor, the ethics committee and the regulatory authorities in the field.

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You are free, if you want, to give up participation in the research, even without a particular reason related to an adverse event.

Also, for any medical reason or lack of compliance with the research visits, the child doctor may withdraw you from this research if he/she believes that it would be beneficial to you. If you are withdrawn from the research for medical reasons, modified parameters will be monitored until normalized and noted at the end of the research.

CONSENT STATEMENT

I declare that I read carefully and understood all the information that was made available to me.

The Doctor explained to me in detail all the benefits and the risks that could arise during this research and answered all my questions.

Undersigned ……..

I voluntarily consent to my child participating in this research, thereby I understand to follow the doctor's indications about the research and to participate together with the child in all related activities, as described in the Data Collection Plan.

Volunteer's signature: .....
Date: ... / ..... /.....

My signature confirms that I have explained to the legal representative of the child all the therapeutic implications, including the possible hazards that might occur by participating in the research.

Investigator: .....
Signature: .....

Date: ... / ...../ .....

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