

Pharmacy-Led Case Study: Immune Support in Children with Recurrent Upper Respiratory Tract Infections (URTIs) Using Imunoglukan P4H®

Parent / Legal Guardian Information Sheet

We would like to invite you and your child to take part in a pharmacy-led case study. Before you decide, it is important that you understand what the case study involves and what taking part would mean for you and your child.

Please read this information carefully and keep it for your records.

1. What is this case study about?

The purpose of this case study is to see if a nutritional supplement called Imunoglukan P4H®, which contains beta-glucan from oyster mushrooms, can support children's immune health. We want to understand whether taking this supplement over three months can reduce the number of coughs, colds, and other upper respiratory infections children experience, helping them stay healthier, attend school more regularly, and enjoy their everyday activities.

The supplement is already on sale in the UK and is provided free of charge as part of this case study. This activity is observational and does not involve medical testing or changes to usual care.

2. Why has my child been invited?

Your child has been invited to take part because they frequently experience respiratory infections such as coughs, colds, earaches, or sore throats, and because you, as their parent or legal guardian, are able to give consent and complete short questionnaires on their behalf.

3. Do we have to take part?

No, taking part is entirely voluntary. If you decide to participate, you are free to withdraw your child at any time without giving a reason and without any impact on your child's care or relationship with the pharmacy.

4. What will taking part involve?

Consent and Baseline Information

If you choose to take part, you will be asked to provide consent after reading this information sheet by completing the consent form on the webpage. You will then be asked to complete a short baseline questionnaire to capture key background information. This will include your child's age, gender, weight, height, school year, recent history of upper

respiratory tract infections (URTIs). Social and healthcare impacts will also be considered in the questionnaires capturing the frequency of primary care visits and medication use (including OTC drugs and antibiotics) in the past 3 months.

Supplement Use

Your child will receive a 3-month supply of Imunoglukan P4H®, sent directly to your home at no cost.

Imunoglukan P4H® is a liquid food supplement that is already sold in the UK. It is taken once a day, with the amount based on your child's weight.

Normally, the dose is 1 ml for every 5 kg of body weight. If your child becomes unwell, a higher dose of 2 ml for every 5 kg can be given once daily for 3 to 7 days.

Don't worry about calculating the dose as clear, personalised instructions will be provided with the supplement.

In-Study Questionnaires

During the three-month period, parents or legal guardians will be asked to complete short online questionnaires only when their child becomes unwell and during the course of that illness episode. The questionnaires will capture information about the symptoms, how long the illness lasts, and any impact on daily activities such as school attendance, use of antibiotics, over-the-counter medicines or any visits to the GP or Pharmacy.

Questionnaires will be completed via the study website. Parents will receive email reminders twice per week, which act as prompts to report if their child is currently unwell. No questionnaires are required when the child is well.

There will be no clinic visits, no physical examinations and no changes to your child's usual healthcare. You should continue to manage your child's health as normal and seek medical advice whenever needed.

5. What are the possible risks?

Imunoglukan P4H® is generally well tolerated. As with any food supplement, mild side effects such as stomach upset or mild allergic reactions may occur, although these are uncommon.

If you have any concerns, seek medical advice as appropriate.

If your child becomes unwell or you have concerns, you should stop the use of the supplement and seek advice from your usual healthcare provider. You should also inform the study team.

6. What are the possible benefits?

Your child may or may not experience direct benefit. However, taking part may help improve understanding of how immune support can be used in pharmacies to support children's health and reduce repeat winter illness.

7. What if there is a problem?

If you have a concern about any aspect of this study, you should speak to the research team who will do their best to answer your questions.

While we prioritise participant safety, if your child is harmed due to our negligence during the study, you may have grounds for legal action. Imunoglukan P4H® is generally safe but, like all supplements, carries a small risk of unexpected reactions. Contact us immediately with any concerns about your child's well-being. We're committed to promptly addressing any issues that arise.

In the event of your child developing an adverse reaction, side effect or complication because of your participation in the study, elénzia MEDICAL has a responsibility to ensure the adverse event is managed properly and resolved satisfactorily. If required agreed costs of medical treatment will be provided and you will be appropriately compensated for any adverse reaction, side effect or complication which is a direct result of your child's participation in this study. In this unlikely event, compensation will be paid on a "no-fault basis".

8. Will taking part in this study be kept confidential?

We will collect some personal information, such as your name, address, and email, only to send the study supplements and communicate about the study. Your child's details like age, weight, height, and gender will be used for analysis, but all results will be anonymised.

All information is provided securely through online questionnaires. Only authorised members of the study team and participating pharmacists can access personal information, and all data will be handled in line with UK GDPR and the Data Protection Act 2018.

You can withdraw from the study at any time without giving a reason. If you ask, we will delete your personal information within 28 days.

At the end of the study, you will receive a personalised report of your child's results by email within 28 working days. All personal data related to this report will be deleted within 180 days. A separate anonymised report, which contains no personal information, may also be shared with participating pharmacies and could be used for marketing or educational purposes.

We will only keep your email if you have agreed to hear about future studies.

To withdraw or request deletion of your data, contact info@ingredients4life.co.uk.

9. What happens when the case study ends?

At the end of the 3month period, responses will be analysed and summarised at group level. Findings may be shared with participating pharmacies and used for education or service evaluation. No child will be identifiable in any reports.

10. Who is organising this case study?

elénzia MEDICAL is responsible for the design and delivery of this pharmacy led case study.

11. Contact for further information

If you would like any further information about this study, please contact:

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