Immunomodulatory effect of pleuran (β-glucan from *Pleurotus ostreatus*) in children with recurrent respiratory tract infections

(IPRRTI study)

NCT number: NA

Informed Consent form
GDPR Consent form

Informed Consent form

(Information for the patient)

Dear Madam, Sir,

We offer you the **opportunity to participate with your child in a clinical study, the aim of which is to evaluate the preventive effect of the food supplement Imunoglukan P4H® chewable tablets on the occurrence of morbidity in children with recurrent respiratory tract infections.**

Respiratory tract infections (RTIs) are the most common cause of morbidity in all age categories, especially in childhood. At the same time, they are the most common cause for the consultations and visits to the attending physician/pediatrician. Recurrent upper respiratory tract infections are predominant, and lower respiratory tract infections are observed in about 10-30%. The most common cause agent are viruses (90-95%).

Due to their high incidence, recurrent respiratory tract infections have a significant socio-economic impact (affecting quality of life, absence from school, missed days at work, repeated medical examinations, hospitalization, as well as increased need for antibiotics).

The treatment of recurrent respiratory tract infections consists of not only the treatment of individual infections, but should be focused mainly on their **prevention**. The treatment and preventive strategy should be aimed at supporting weakened functions of the immune system, e.g., by immunomodulation.

Endpoints:

The aim of the study is to evaluate the preventive effect of Imunoglukan P4H® chewable tablets on reduction of the number and duration of respiratory infections in patients with recurrent respiratory infections during the infectious season. Other study objectives include evaluation of treatment tolerance, the number of missed days at school/nursery or at work, and the need for antibiotic treatment, emergency department visits and physician visits.

The efficacy of the study product will be evaluated compared to the placebo group:

- **Active group:** Imunoglukan P4H® chewable tablets (1 tablet contains 50 mg IMG®, 5 mg zinc and 10 µg vitamin D)
- **Control group:** Placebo chewable tablets (1 tablet contains 5 mg zinc and 10 µg vitamin D)

If you decide to participate in the study, your child will **be randomly assigned** to one of 2 groups (active group or placebo group). The probability of inclusion in any of the groups will be the same. This means that out of 2 participants, 1 patient receive Imunoglukan P4H® chewable tablets and 1 patient receive the corresponding placebo chewable tablets in the dose:

- up to 25 kg of body weight 1 tablet once a day for 3 months
- over 25 kg 2 tablets 1once a day for 3 months

The study in which you and your child will participate will last **3 months.** You will undergo the first visit together with inclusion into the study **during a standard visit to your physician**. Subsequently, you will undergo 3 control visits after the 1st, 2nd and 3rd month from the inclusion in the study. At the last visit, after 3 months, your participation in this study will be terminated. Throughout the entire duration of the study, you will **continuously keep a patient diary,** in which you will record the incidence and duration of symptoms of **respiratory infections in your child.**

During the study period, please **do not give your child other immunomodulators regularly and long-term** (e.g., beta-glucans, echinacea, nucleotides, bacterial lysates, vitamin C and D, selenium, zinc and others) that could affect the results of this study.

In case your child gets sick during the study, it will be treated according to the standard procedures recommended by your attending physician, whom you should contact immediately. All participants in this study are insured.

The results will only be used in anonymized form for study purposes. The overall results of the study will be published in the scientific literature.

Participation in this study is voluntary, is freely carried out, while preserving the right to protection of dignity, to respect the physical and psychological integrity, safety and legitimate interests of the study participant. After all details of the study have been explained by your attending physician and after reading this informed consent, you are free to decide whether or not to participate in the study.

- You can terminate your participation in the study at any time, even without giving a reason, i.e., you can withdraw your informed consent at any time without giving a reason.
- Your doctor also has the right to exclude you from the study in case of your non-cooperation or intolerance to the preparation.
- The data obtained during this study are confidential and subject to confidentiality.
- Refusal to participate in study, termination of participation in study – withdrawal of the study participant's Informed Consent, will not adversely affect the provision of health care and will not mean other adverse consequences for your child on the part of healthcare professionals.
- Participation in the study will be free of charge.

I hereby confirm that I have read the information regarding the above study and have had the opportunity to request details and ask questions about this issue. I declare that I have understood the information and explanations provided, and based on the information provided and my free will, **I agree to my child's participation in study** focused on evaluating the preventive effect of long-term administration of a food supplement Imunoglukan P4H® chewable tablets in patients with recurrent respiratory tract infections.

This Informed Consent is made in two copies, one copy is for the patient/legal representative and the other for the physician, and will be included in the documentation of the study participant.

Name of legal representative: .....

Signature of legal representative: .....

Telephone contact of the legal representative: .....

Name of physician: .....

Signature of physician: .....

In..... Date: .....

GDPR Consent form

(Consent to personal data processing)

I, the undersigned ..... give, to authorized persons – physicians performing the relevant study, my explicit consent to the processing of personal data of my child in accordance with § 5 letter a) and in accordance with § 14 of Act no. 18/2018 Coll. on the protection of personal data and on the amendment of certain laws for the following purposes:

- carrying out the relevant study
- processing, evaluation, publication of study results
- archiving for the period specified by law (at least 15 years)
- research, scientific, pedagogical and publishing activities

The period of validity of my consent to the use of data for the above-mentioned purposes is set for five years.

Consent is granted to the processing of personal data relating to my child to in the scope of name, surname, date of birth, gender and data about my child´s health status when processed in source documentation by the attending physician in written and electronic records. N**o one except the attending physician and his or her associates will have access to information that enables the identification of my child.**

Name of legal representative: .....

Signature of legal representative: .....

In..... Date: .....