

Name of the medicinal product: ANTI-PSEUDOMONAS IgY

Developer: IMMUNSYSTEM AB

Solution for gargling and swallowing, 70 ml

Active ingredient: Polyclonal IgY chicken antibodies against *Pseudomonas aeruginosa*

Medication must be kept frozen (-15 to -40°C)!

Product Information

Contents of the medicinal product or placebo

Both the medicinal product (anti-*Pseudomonas* IgY) and the placebo are gargling solutions. The manufacturing process for both solutions is identical. Only the starting material (egg yolk) differs in terms of its efficacy against the germ *Pseudomonas aeruginosa*. Both solutions are extracts of the water-soluble fraction of egg yolk, which in the case of the medicinal product contains the active ingredient (anti-*Pseudomonas* IgY) against *Pseudomonas aeruginosa*. The placebo does not contain any IgY antibodies against *Pseudomonas aeruginosa*.

Mechanism of action

It is assumed that the active ingredient forms a barrier against *Pseudomonas aeruginosa* germs in the mouth and throat of the patients. If *Pseudomonas aeruginosa* penetrates through the mouth or nose, this antibody barrier prevents the germs from adhering to the epithelial cells. By gargling with anti-*Pseudomonas* IgY after the last meal and drink and after tooth-brushing in the evening, the active ingredient remains in the mouth throughout the whole night and protects against the adherence of the germs. In this way, it is assumed, the germs are prevented from penetrating into the respiratory tract. By swallowing the solution with the active ingredient after gargling it is also intended to prevent infection by bacteria that are already present in the gastrointestinal tract.

Intended use

Anti-*Pseudomonas* IgY is a medicinal product that is designed to prevent *Pseudomonas* infections in patients with cystic fibrosis. The medicinal product may be used as part of the PsAer-IgY study in cystic fibrosis patients with *Pseudomonas* verified in one or more sputum or throat cough swab or endolaryngeal suction samples but who do not show signs of chronic infection.

Instructions for use

During your inclusion visit, at the doctor's office-, you will receive 7 boxes each containing 15 bottles of the solution to be taken. One bottle corresponds to a daily ration. At each later regular study visit you will receive a further 6 boxes. The bottles and the boxes should not be stored separately and must be kept in the freezer at a temperature of at least -15°C to -40°. You may transport the bottles with the solution from the visit to home in a normal unchilled bag. Once you arrive home, you should immediately place the bottles in the freezer, but please remember to leave one bottle out for use on the first evening. The bottles should be thawed at room temperature. Each morning you should take one bottle of IgY/placebo from the current box (the boxes are numbered sequentially) and thaw the solution at room

temperature for use in the evening. Please do not thaw in the microwave! Do not open the bottle more than 2 hours prior to use.

Every evening you will gargle for 2 minutes with 70 ml of the anti-Pseudomonas IgY solution that is in the bottle after tooth-brushing. The solution can be divided into 2–4 portions; the total gargling time should be 2 minutes. After gargling please ensure you swallow the solution. If possible, you should not eat or drink after gargling until the next morning. You should repeat the daily gargling until the end of the study. The study ends for you if *Pseudomonas aeruginosa* is detected in your sputum or throat cough swab or endolaryngeal suction sample or after a maximum of 24 months.

What do you do if you have forgotten to gargle once?

Daily gargling should not be forgotten more often than three times each month (and not in a row). If you have forgotten to gargle once, please ensure that you gargle the next morning as soon as possible after breakfast so that the solution can form a protective film against possible bacterial adherence at least until the next meal. You may eat your meals at the usual time on this day. You must not forget, however, to gargle again on the same evening. If you forget to gargle on two or more consecutive days, please inform the study centre so that an appointment can be made to take a new sputum or throat cough swab or endolaryngeal suction sample. Please follow the treatment plan as usual until the result of this test is available. If *Pseudomonas aeruginosa* cannot be detected in the sputum or throat cough swab or endolaryngeal suction, you can continue the study as normal, otherwise the study ends. Please record your intake of the solution every day in the diary provided for you.

Who should not take the solution?

If you have a verified allergy against hens' egg protein, he or she should not take the solution.

Known side effects

In patients without an allergy to hens' egg protein there are no known side effects. Because eggs form a normal part of the diet, there is practically no risk of negative effects of the IgY antibodies located in the solution with the drug. During the study all unexpected reactions in terms of your health should be documented in the diary provided and the attending doctor should be informed.

Storage and shelf life

Anti-Pseudomonas IgY has a shelf life of 24 months if it is stored at a temperature of at least -15°C to -40°C. Unopened bottles can be stored in the refrigerator for up to one week and at room temperature for 1–2 days. To make transporting the bottles with the solution easier, it is possible to transport the bottles unchilled. To do this the solution can be thawed once and frozen again. Opened bottles must be used within 2 hours. If during the study you will not be home for a period longer than 2 days (e.g., on holiday), please check that you will be able to store the bottles with the solution in the refrigerator or in the freezer for longer absences at the place where you will be staying. Any exceptions which may be granted on the basis of the stability data available, must be discussed carefully with your doctor in advance.

Please do not throw empty bottles away but collect them and bring them (together with the boxes) to the next study visit so that they can be counted.

Further information:

Sponsor (responsible for the study):

Mukoviszidose Institut gemeinnützige
Gesellschaft für Forschung und Therapieentwicklung mbH
In den Dauen 6
53117 Bonn, Germany

Manufacturer: Cobra Biologics

Storjordenvägen 2
SE-864 31 Matfors
Sweden

Important instructions

The medicinal product / placebo should be kept frozen until the day it is used.

As an exception the medicinal product / placebo may be stored for up to one week in the refrigerator if necessary. Any exceptions from the storage conditions described in this document must be discussed carefully with your doctor in advance.

Please ensure that you gargle every evening after tooth-brushing with the medicinal product / placebo and then swallow the solution.

Please fill out the diary given to you so that you can document your consumption of the medicinal product or placebo and your health (including any possible side effects of the medicinal product).

Please keep in regular contact with your attending doctor (investigator).