

## **Pneumococcal infections and vaccination - questions and answers**

### **What causes pneumococcal infections or diseases?**

Pneumococcal infections are caused by the bacterium *Streptococcus pneumoniae* (pneumococcus). There are more than 90 serotypes of this bacterium, most of which can cause diseases.

### **How is the infection transmitted and who is at higher risk of developing the disease?**

Pneumococci are normally present in the mucous membranes of the respiratory tract. They are especially found in the nose and throat. They are transmitted from person to person through infectious droplets produced when someone sneezes or coughs. In addition to the presence of the bacterium, reduced immunity is also important for the development of the disease. Young children, the elderly, people with chronic diseases and immunodeficiency are particularly at risk. The risk of pneumococcal disease is also increased by previous viral respiratory infections that weaken local immunity.

### **How long is someone with a pneumococcal infection contagious?**

The exact duration of contagiousness is unknown. It appears that transmission can occur as long as pneumococcus is present in respiratory secretions. For the spread of pneumococcus, healthy carriers are more important than patients.

### **What diseases can pneumococcus cause?**

Pneumococcal pneumonia can cause sinusitis, otitis media, pneumonia, blood infections (bacteraemia, sepsis) and inflammation of the meninges (meningitis). Some serious pneumococcal infections (invasive pneumonia, sepsis, meningitis) can be fatal.

Otitis media is the most common pneumococcal infection in children. It manifests itself with ear pain, redness and tension in the eardrum, possibly discharge from the ear and elevated body temperature. In infants, it can also cause irritability and diarrhoea.

Pneumococcal pneumonia can occur 1–3 days after infection. The illness onset is sudden and manifests itself with chills, elevated body temperature, cough with yellow purulent sputum, sharp chest pain that worsens with deep inhalation, heavy and/or rapid breathing, elevated heart rate and weakness. The mortality rate is 5–7%, and can reach over 50% in the elderly.

Sepsis is blood infection that is fatal in 4 out of 100 children. The mortality rate is even higher in older people.

Pneumococcal meningitis is characterised by headache, fatigue, vomiting, irritability, elevated body temperature, stiff neck, neurological deficits, convulsions and coma. The mortality rate of patients with pneumococcal meningitis is around 10%. Neurological sequelae are common in survivors.

### **How common are invasive pneumococcal infections in Slovenia?**

Pneumococcal infections are most common in children under 5 years of age and in older people (aged 65 and older). The highest number of infections is recorded in children aged one year, namely in one in every thousand to two thousand children per year. In other age groups, pneumococcal infections are less common. In Slovenia, 18 people died in 2023 due to invasive pneumococcal infections.

In Slovenia, the incidence of invasive pneumococcal infections is higher than in many European countries, where the introduction of routine pneumococcal vaccination has led to a significant reduction in infection rates.

### **What is the treatment for pneumococcal infections?**

Pneumococcal infections are treated with antibiotics. Recently, pneumococci have become resistant to antibiotics has been emerging, which makes treatment more difficult. For this reason, it is important to follow the instructions of your doctor and pharmacist when taking antibiotics, and it is particularly important to prevent infections, especially through vaccination.

### **Can one get ill with pneumococcal infection more than once?**

Yes. Recovery from infection with one of the 90 serotypes of pneumococci does not confer immunity to infection with other serotypes. Vaccination is also recommended if an individual has had one or more episodes of invasive pneumococcal infection.

### **Is there a vaccine against pneumococcal infections?**

Yes. There are several types of pneumococcal vaccines (conjugate and polysaccharide). In Slovenia, a 20-valent conjugate vaccine is used for the vaccination programme, which prevents infection with the serotypes of pneumococci that most commonly cause invasive diseases. The 20-valent vaccine is used for children as well as for older adults and chronic patients.

### **What is specific to polysaccharide vaccine?**

The first polysaccharide vaccine became available in the 1970s. The polysaccharide vaccine that protects against 23 serotypes of pneumococci has been available since the 1980s, including in Slovenia. It was intended to protect persons aged 2 years and older who were at increased risk of invasive pneumococcal infection. These are people who have chronic diseases, especially chronic diseases of the circulatory system, respiratory system, urinary tract, liver, metabolic diseases (diabetes, etc.), certain neuromuscular and connective tissue diseases, malignant diseases, certain diseases of the blood and blood-forming organs, and diseases and conditions that weaken the immune response. The vaccine was also intended for all people aged 65 and over.

### **What is specific to conjugate vaccines?**

The first conjugate vaccine became available in 2000. A conjugate vaccine against 13 serotypes of pneumococci (13-valent vaccine) has been available in Slovenia since 2010 and a conjugate vaccine

against 20 serotypes of pneumococci (20-valent vaccine) has been available since 2023. Conjugate vaccines stimulate a better immune response than the polysaccharide vaccine.

The 13-valent conjugate vaccine was intended to prevent invasive diseases, pneumonias and acute otitis media caused by pneumococcus in infants, children and adolescents aged 6 weeks to 17 years, while the 20-valent conjugate vaccine is also intended to prevent invasive diseases and pneumonias caused by pneumococcus in adults aged 18 years and older.

#### **Do pneumococcal vaccines contain aluminium?**

The 20-valent conjugate vaccine contains a small amount of aluminium salt (aluminium phosphate), which is important for a better immune response to the vaccine.

Aluminium is one of the most widespread metals in our environment. It is found in water, air, food, cosmetics, medicines and even in breast milk. Food is the main source of aluminium that we take into our bodies. Aluminium has been used in vaccines as an immune response enhancer (adjuvant) for more than 70 years. Administration of the vaccine into the muscle does not cause any noticeable changes in the concentration of aluminium in the blood. Almost all of the aluminium is rapidly eliminated from the body.

#### **Do pneumococcal vaccines contain thiomersal?**

No.

#### **What is the routine vaccination scheme for children against pneumococcal infections?**

Children are routinely vaccinated with a 20-valent conjugate vaccine. Vaccination of children starts at 3 months of age, simultaneously with the hexavalent vaccine (against diphtheria, tetanus, whooping cough, Haemophilus influenzae type b, polio and hepatitis B). The second dose is given to children together with the second dose of the hexavalent vaccine at 5 months of age and the third dose at 6 months of age. The booster dose is given between 11 and 18 months of age.

#### **Can I wait to vaccinate until my child is one year old?**

In Slovenia, invasive pneumococcal diseases most commonly affect children in their second year of life, followed by children under one year of age. Therefore, the greatest benefit in preventing these infections through vaccination is achieved when children are vaccinated at the recommended age and vaccination is not delayed.

#### **What are the vaccination schemes for children older than 5 years and adults?**

Vaccination against pneumococcal infections is not routinely recommended for healthy persons between 5 and 64 years of age, but is possible with a single dose of vaccine. Vaccination against pneumococcal infections is recommended for people aged 65 years and older and for chronic patients, as they are at higher risk of developing invasive pneumococcal infections or pneumonia. For children over 5 years and adults, the recommendations in the flowchart at the following link apply.

### **How is the vaccine administered?**

The pneumococcal vaccine is administered to children younger than two years of age by intramuscular injection into the front of the thigh. For children older than two years, the vaccine is administered by intramuscular or subcutaneous injection into the upper arm.

### **Who recommends vaccination against pneumococcal infections?**

Vaccination against pneumococcal infections is recommended by the following institutions and organizations: National Institute of Public Health (NIJZ), the Vaccination Advisory Group, the Slovenian Paediatric Association of the Slovenian Medical Association (SZD), the Clinic for Infectious Diseases and Febrile Conditions of the University Medical Centre Ljubljana, the European Centre for Disease Prevention and Control (ECDC), the World Health Organisation (WHO), and many other professional associations both domestic and foreign.

### **How effective are the vaccines against pneumococcal infections?**

Vaccines against pneumococcal infections have been shown to be effective in clinical trials.

Studies have shown that the immune response to the 20-valent conjugate vaccine in people aged 60 years or older is good compared to the 13-valent conjugate vaccine. Studies have also shown that the immune response to the 20-valent conjugate vaccine is at least as good or better in people aged 60 years or older than to the 23-valent polysaccharide vaccine (for 6 of the 7 additional serotypes common to the two vaccines). The immune response to the 20-valent conjugate vaccine (for all 20 serotypes) was also good in persons aged 18–59 years. In infants aged approximately 2–15 months, the 4-dose PCV20 scheme elicited a strong immune response against all 20 serotypes included in the vaccine.

### **How safe are vaccines against pneumococcal infections?**

Vaccines against pneumococcal infections have been shown to be safe in clinical trials. The risk of complications from the disease is significantly higher than the risk of serious side effects after vaccination.

The most commonly reported symptoms after vaccination with pneumococcal vaccines were local reactions at the injection site (redness, pain, and swelling), elevated body temperature, muscle and joint pain, headache, temporary loss of appetite, irritability, restless sleep, fatigue and drowsiness, vomiting, diarrhoea and rash. Serious adverse events were rare.

Adverse events of pneumococcal vaccination are regularly monitored by public health institutions (in Slovenia, reports are collected by the Register of Adverse Events after Vaccination at the NIJZ), the Slovenian Agency for Medicinal Products and Medical Devices, the European Medicines Agency and manufacturers.

### **Can the vaccine cause pneumococcal infection?**

No. Pneumococcal vaccine is dead and contains only purified particles of the microbe, therefore it cannot cause pneumococcal infection.

**Is vaccination against pneumococcal infectious with a 20-valent conjugate vaccine recommended even if the person has already been vaccinated against pneumococcus with another vaccine in the past?**

Patients with compromised immunity, anatomical or functional splenia, a cerebrospinal fluid fistula or a cochlear implant, aged 5 years or over, should be vaccinated with the 20-valent conjugate vaccine, even if they have previously received the 13-valent conjugate or 23-valent polysaccharide vaccine against pneumococcus. The vaccination is administered in a single dose and is covered by compulsory health insurance.

Based on the judgement of the attending physician, older adults (aged 65 and above) and chronic patients, aged 5 and older, who have already been vaccinated with the 13-valent conjugate or 23-valent polysaccharide pneumococcal vaccine, may be vaccinated with a single dose of the 20-valent conjugate vaccine at the expense of compulsory health insurance.

In these cases, vaccination with PCV20 is performed at least 1 year after the last dose, and in persons up to 18 years of age, at least 8 weeks after the last dose.

**Can a pregnant or breastfeeding woman receive the pneumococcal vaccine? How does the vaccine affect fertility?**

The recommendation is not to vaccinate pregnant women with this vaccine unless there is a high risk of infection. Women at high risk of invasive pneumococcal disease should be vaccinated before becoming pregnant, if possible. Unvaccinated pregnant women at high risk should consult their doctor about possible vaccination.

**Who should not receive the vaccine against pneumococcal infections?**

Persons who have had a severe allergic (anaphylactic) reaction after a previous dose of the same vaccine or who are severely allergic to any of the vaccine components should not be vaccinated against pneumococcal infections. If a person is moderately or seriously ill with elevated body temperature, vaccination is temporarily delayed until recovery. People with mild illness (e.g. cold) can be vaccinated.

**Where can I find out more about vaccines against pneumococcal infections?**

For more information about these vaccines, see the summaries of product characteristics (SmPC), section Instructions for use: <https://www.ema.europa.eu/en/medicines/human/EPAR/apexxnar> (20-valent conjugate vaccine).