

## **On protective immunization against pneumococcal diseases in infants/small children – with conjugate vaccine**

Pneumococcal infections are caused by *Streptococcus pneumoniae* bacteria. There are more than 90 serotypes, but not all of them are dangerous to humans. The pathogens are transmitted by droplet infection. Ca. 10% of all adults and an even higher percentage of children have Pneumococci in the nasopharyngeal cavity (nose and throat region). They are healthy bacteria carriers without disease symptoms. An impairment of the local or general immune defenses can lead to the pathogens reproducing and to a pneumococcal disease, especially to pneumonia and meningitis, blood poisoning, inflammation of the middle ear and sinuses. These bacteria can cause life-threatening infections, especially in children in the first years of life and in elderly persons, as well as in people of all age groups with weakened immune systems or chronic diseases. Meningitis can result in severe permanent damage to the central nervous system or hearing loss.

### **Vaccine**

The two pneumococcal vaccines discussed here are known as conjugate vaccines. They are produced by a special technique and are highly effective and well-tolerated, even in very young children. They contain parts of the bacterial cell envelope (polysaccharides) of the pathogen and target the most common types of the pathogen that cause pneumococcal diseases in this country. The pneumococcal conjugate vaccines act against severe invasive pneumococcal diseases (blood poisoning, meningitis, and pneumonia) and also against inflammation of the middle ear.

In Germany there are two different conjugate vaccines available: Prevenar 13® targets 13 serotypes and is approved for children older than 6 weeks, adolescents, and adults. Synflorix® targets 10 serotypes and can be used in children from 6 weeks to five years old.

The vaccine is injected into muscles (intramuscular injection). The vaccination intervals are largely the same for both vaccines. Depending on the age, 1 to 3 injections are required for complete protective immunization: the younger the child, the greater the number of vaccinations necessary in order to maintain effective protective immunization, which is especially important for young infants. Premature infants receive a total of 4 vaccinations. Your doctor can explain the exact procedure to you.

In early childhood, the pneumococcal vaccine can be co-administered with the other recommended vaccines, but at different sites (e.g., right and left thigh, right and left upper arm); co-administration will not adversely impact tolerance and efficacy. You doctor can tell you when protective immunization starts and how long it lasts.

### **Who should get vaccinated?**

The pneumococcal vaccine is recommended for all children up to 24 months of age, and as early as possible.

Furthermore, all persons over the age of 60 should be vaccinated against Pneumococci. A pneumococcal vaccination is also recommended for children, adolescents, and adults with increased health risks due to an underlying disease.

Besides the conjugate vaccines, a so-called polysaccharide vaccine is also available for the pneumococcal vaccination of children over the age of 2, adolescents, and adults. The vaccinator will advise you on choosing the appropriate vaccine.

**Who should not get vaccinated?**

Vaccination must be postponed until recovery in the event of an acute disease with a fever that requires treatment. However, ordinary infections are no reason not to vaccinate. If strong vaccine reactions occurred after an earlier vaccination with the same vaccine or in the event of a known hypersensitivity to one of the vaccine components, the vaccinator will advise you concerning the need and the possibility of other vaccinations.

In patients suffering from a heightened tendency to bleed and who therefore should not receive intramuscular injections, an individual risk/benefit assessment is required before administering this vaccine and if necessary another injection technique must be used.

**Behavior after the vaccination**

The vaccinated individual does not require any extra care, but should avoid unaccustomed physical activity for 3 days after the vaccination. Regarding persons with a tendency to cardiovascular reactions or with a known history of immediate hypersensitivity (type 1 allergies), the doctor should be informed accordingly before the vaccination.

**Possible local and general reactions after the vaccination**

Along with the desired immunity and the protection from the disease, after the vaccination ca. 1 out of 10 vaccinated persons may experience redness or painful swelling at the vaccination site. This is an expression of the body's normal interaction with the vaccine and usually occurs within 2 to 3 days and seldom lasts for long. These reactions at the vaccination site are often linked with a palpable lump and sensitivity to pressure, which interferes with movement.

General symptoms such as fever of 39°C and higher, irritability, drowsiness, restless sleep or gastrointestinal troubles (e.g., loss of appetite, vomiting, diarrhea), rashes, joint or muscle pain can also occur within 1 to 3 days, and headaches are also common. These symptoms rarely last for long. Pressure sensitivity, often accompanied by limited mobility, has been observed more frequently after booster vaccinations (i.e., the 3<sup>rd</sup> or 4<sup>th</sup> vaccine dose) in small children and also when vaccinating adults.

As a rule vaccine reactions are temporary and subside quickly with no further consequences.

**Are vaccine complications possible?**

Vaccine complications are very rare consequences of vaccination that go beyond the normal degree of a vaccine reaction. They have substantial adverse impacts on the health of the vaccinated person. In isolated cases there may be an increase in temperature associated with febrile spasms in young infants or small children. As a rule these subside without any consequences. Brief shock-like states with nonresponsiveness and atonic musculature have been observed after vaccination in infants or small children, but only in isolated cases. These subside rapidly and without any consequences.

Rarely, an allergic reaction of the skin (e.g., hives, itching) or respiratory passages may occur after vaccination with pneumococcal conjugate vaccine, and in isolated cases may lead to shock.

Isolated complications such as febrile reactions or temporary seizures may occur more often in infants and small children when pneumococcal conjugate vaccines are co-administered with six-fold vaccines. Your doctor can advise you on this.

**Advice by the vaccinator on possible side effects**

As a supplement to this fact sheet, your doctor will propose an informational discussion to you.

Obviously the vaccinator will also be available to you for advice if symptoms occur after a vaccination that go beyond the above-mentioned rapidly subsiding, temporary local and general reactions.

You can reach the vaccinator:

**Disclaimer**

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Name \_\_\_\_\_

Name

### Protective immunization against pneumococcal diseases – with conjugate vaccine

*Schutzimpfung gegen Pneumokokken-Erkrankungen – mit Konjugatimpfstoff*

Enclosed you will find a fact sheet on protective immunization against pneumococcal diseases with conjugate vaccines. It contains key information on the diseases preventable by the vaccination, the vaccine, the vaccination and on vaccine reactions and possible vaccine complications.

*Anliegend erhalten Sie ein Merkblatt über die Durchführung der Schutzimpfung gegen Pneumokokken-Erkrankungen mit Konjugatimpfstoff. Darin sind die wesentlichen Angaben über die durch die Impfung vermeidbaren Krankheiten, den Impfstoff, die Impfung sowie über Impfreaktionen und mögliche Impfkomplicationen enthalten.*

The following additional information will be requested before the vaccination:

*Vor der Durchführung der Impfung wird zusätzlich um folgende Angaben gebeten:*

1. Is the person getting vaccinated currently healthy?

*Ist der Impfling gegenwärtig gesund?*

Yes (Ja)

No (Nein)

2. Does the person getting vaccinated have any known allergies?

*Ist bei dem Impfling eine Allergie bekannt?*

Yes (Ja)

No (Nein)

If yes, specify \_\_\_\_\_

*wenn ja, welche*

3. Did the person getting vaccinated experience allergy symptoms, high fever, or other unusual reactions after a previous vaccination?

*Traten bei dem Impfling nach einer früheren Impfung allergische Erscheinungen, hohes Fieber oder andere ungewöhnliche Reaktionen auf?*

Yes (Ja)

No (Nein)

Ask the vaccinator if you would like more information on protective immunization against Pneumococci (with conjugate vaccines)!

*Falls Sie noch mehr über die Schutzimpfung gegen Pneumokokken – mit Konjugatimpfstoff – wissen wollen, fragen Sie den Impfarzt!*

Please bring your vaccination records when you come for your vaccination appointment!

*Zum Impftermin bringen Sie bitte das Impfbuch mit!*

**Declaration of consent***Einverständniserklärung***to protective immunization against pneumococcal diseases – with conjugate vaccine***zur Durchführung der Schutzimpfung gegen Pneumokokken-Erkrankungen – mit Konjugatimpfstoff*

Name of the person being vaccinated \_\_\_\_\_

*Name des Impflings*

Date of birth \_\_\_\_\_

*geb. am*

I have read and understood the content of the fact sheet and have been informed in detail about the vaccination by my doctor in the discussion.

*Ich habe den Inhalt des Merkblatts zur Kenntnis genommen und bin von meinem Arzt/meiner Ärztin im Gespräch ausführlich über die Impfung aufgeklärt worden.*

I have no further questions.

*Ich habe keine weiteren Fragen.*

I give my consent to the proposed vaccination against pneumococcal diseases – with conjugate vaccine.

*Ich willige in die vorgeschlagene Impfung gegen Pneumokokken-Erkrankungen – mit Konjugatimpfstoff – ein.*

I refuse the vaccination. I was informed about the possible disadvantages of refusing this vaccination.

*Ich lehne die Impfung ab. Über mögliche Nachteile der Ablehnung dieser Impfung wurde ich informiert.*

Notes *Vermerke* \_\_\_\_\_Place, date *Ort, Datum* \_\_\_\_\_\_\_\_\_\_  
Vaccinated person's or legal guardian's signature*Unterschrift des Impflings bzw. des Sorgeberechtigten*\_\_\_\_\_  
Doctor's signature*Unterschrift des Arztes/der Ärztin*