

**about vaccinations against tetanus, diphtheria, pertussis (whooping cough), Haemophilus influenzae b (Hib), poliomyelitis (polio), and hepatitis B**

Vaccinations against tetanus, diphtheria, whooping cough, Hib, polio, and hepatitis B are generally recommended during infancy and early childhood.

Even modern treatment options cannot always prevent the often-fatal courses and long-term effects these infectious diseases may have in unvaccinated people. Only vaccinations performed on schedule can offer protection against them.

It makes sense to use a combination vaccine for protection against these six diseases: the number of injections required to protect against them are reduced, and the vaccination passport schedule is clearer and easier to follow. The combination vaccines authorized in Germany are as safe and effective as the single vaccines.

**Lockjaw** (tetanus) is a life-threatening infectious disease. The bacterium is found mainly in dirt and road dust and enters the skin through cuts, cracks, abrasions, or bites, and even through the most minor sites of injury, and then proliferates in the body and forms the tetanus poison responsible for causing the disease. Muscle contractions are characteristic symptoms of this very serious disease and can lead to suffocation attacks when the respiratory muscles are affected. Despite modern treatment methods, over 10 to 20 percent of patients with tetanus die.

**Diphtheria** is a life-threatening infectious disease caused by the poison (toxin) of the diphtheria bacterium, which is transmitted mainly by airborne droplet infection. Before vaccinations were introduced, many children died from the infection that presented as throat, larynx, nose, and wound diphtheria, or they suffered damage to their heart muscle. The high participation in vaccinations has eliminated diphtheria, apart from a few isolated cases, in Germany. However, since it persists globally - including in some Eastern European countries - the risk of re-introduction and re-infection when travelling can occur at any time.

**Whooping cough** (pertussis) usually begins as a cold. It progresses to severe coughing fits, and difficulties with breathing, and vomiting frequently occurs within the first 6 months of age, the characteristic cough may not appear, however respiratory arrest may occur instead; therefore, the infection is particularly dangerous in the first year of life. The rate of serious complications at childhood age is high; particularly pneumonia, middle ear infections, and permanent brain damage may occur.

Diseases caused by the bacterium **Haemophilus influenzae type b** (Hib) are among the most serious infectious diseases during infancy. Meningitis and mucosal inflammation of tissue that covers the trachea and the entrance of the larynx (epiglottitis) that is associated with choking are especially feared. These diseases generally appear between the 5th month and 3rd year of life; after the age of 5, the disease is very rare.

**Polio** (poliomyelitis) is a viral disease that can lead to paralysis of the arms and legs, but also to respiratory paralysis and thus, suffocation. Most patients with paralysis suffer long-term damage. Since 1998, polio vaccinations are no longer performed with an oral vaccine but with a vaccine of killed polio virus (inactivated vaccine). Polio is no longer found in Europe. However, there is continued risk of infection by introduced diseases and when

travelling to polio areas, especially Asia and Africa. Polio vaccinations must therefore be performed consistently, even today.

**Hepatitis B** is virus-induced inflammation of the liver. It can begin with flu-like symptoms, nausea, or joint pain, and later lead to jaundice. The infection can also go unnoticed. Approximately 1% of patients die. The infection becomes chronic in up to 10% of adults; the virus remains in the body and can lead to serious liver damage (cirrhosis, cancer). A chronic course of the disease is much more frequent in those who were infected as small children or infants (approximately 30 or 90%, respectively) by their mothers or by other close contacts. In Germany, approximately 0.5% of the population is chronically infected with the hepatitis B virus. It is transmitted by the blood or body fluids of an infected individual, i.e., also by sexual intercourse.

### **Vaccine**

The combined 6-in-1 vaccine contains these essential components: detoxified toxins of diphtheria and tetanus pathogens, parts of the pertussis bacterium (acellular pertussis), and parts of the envelope protein of Haemophilus influenzae type b bacteria (Hib conjugate vaccine), inactivated poliovirus, and parts of the envelope protein of the hepatitis B virus that was technologically produced in yeast cells. The vaccine is injected into the muscle (intramuscular injection). Your physician can provide you with information regarding the start and length of vaccine protection.

### **Who should be vaccinated and when?**

The immunization passport recommends the combined vaccination against tetanus, diphtheria, whooping cough, Haemophilus influenza type b, polio, and hepatitis B for all children starting at the age of 8 weeks. Vaccinations should be started in early infancy. i.e. at the age of 2, 3 and 4 months, followed by a booster vaccination at 11-14 months. All vaccines doses listed should be administered at the recommended time. Note: booster vaccinations for tetanus, diphtheria, whooping cough, and polio should be given at school age and adulthood according to STIKO recommendations.

### **Who should not be vaccinated?**

Anyone suffering from acute illness with a fever (above 38.5°C) that requires treatment should not be vaccinated. If hypersensitivity to a vaccine component exists or if disease symptoms had appeared following a previous vaccination against one or more pathogens contained in the combination vaccine, the vaccinating doctor will advise parents on the necessity and the possibilities of further vaccinations. This also applies to chronically ill children or to children who are suspected of having a chronic disease.

### **Behavior after vaccination**

The vaccinated person does not require any special attention; however, unusual physical stress should be avoided within 3 days of vaccination. The doctor should be informed prior to vaccination if children are prone to cardiovascular reactions or have known immediate allergic reactions.

**Possible local and systemic reactions following vaccination**

After vaccination, redness or a painful swelling may frequently occur at the injection site in addition to the desired immunity and corresponding disease protection. This is the body's normal reaction to the vaccine and usually occurs within 1-3 days, and seldom persists longer. Occasionally, nearby lymph nodes may become swollen. Occasionally, an entire extremity (leg or arm) may swell up. The overall well-being may also be affected for 1-3 days, and may include temperature increase, influenza-like symptoms (shiver, headache, joint pain, tiredness), or cough, restlessness, irritability, and atypical crying. Likewise, loss of appetite, nausea, vomiting, or diarrhea may occur. A fever of 39°C and above frequently occurs. The above-mentioned reactions are generally temporary and quickly subside without long-term effects.

**Are there possible complications from the vaccination?**

Vaccination complications, beyond the normal extent of a vaccine reaction, are very rare occurrences that have a significant negative impact on vaccinee's health. In isolated cases, children may experience febrile seizures following vaccination with the 6-in-1-vaccine, which usually subside with no long-term effects. Allergic reactions to the vaccine are possible. After vaccination with this combination vaccine, brief shock-like states accompanied by unresponsiveness and slackening of muscles have been observed in individual cases, but quickly resolved with no long-term effects.

**Consultation with the vaccinating doctor about possible side effects**

In addition to this leaflet, your doctor is available for a meeting. In the event that, following a vaccination, symptoms should occur that are beyond the above-mentioned temporary local and general reactions, your immunizing doctor will of course also be at your disposal for advice.

You can reach the vaccinating doctor at:

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Name *Name* \_\_\_\_\_

### Vaccination against Tetanus, Diphtheria, Whooping cough, Haemophilus infl.-Type b (Hib), polio and hepatitis B

*Schutzimpfung gegen Wundstarrkrampf, Diphtherie, Keuchhusten, Haemophilus-infl.-Typ-b-Erkrankungen (Hib), Kinderlähmung und Hepatitis B*

Please find enclosed an information leaflet on the vaccination procedure against tetanus, diphtheria, whooping cough, Hib, polio, and hepatitis B. It contains essential information about the diseases that are preventable by vaccinating, the vaccine, the vaccination, reactions to the vaccine, and possible vaccine complications. Before the vaccination is performed, the following additional information is requested:

*Anliegend erhalten Sie ein Merkblatt über die Durchführung der Schutzimpfung gegen Wundstarrkrampf, Diphtherie, Keuchhusten, Hib-Erkrankungen, Kinderlähmung und Hepatitis B. Darin sind die wesentlichen Angaben über die durch die Impfung vermeidbaren Krankheiten, den Impfstoff, die Impfung sowie über Impfreaktionen und mögliche Impfkomplicationen enthalten.*

Before the vaccination is performed, the following additional information is requested:

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

1. Is the vaccinee currently healthy?

*Ist der Impfling gegenwärtig gesund?*

yes (*Ja*)

no (*Nein*)

2. Has vaccinee experienced a disease of the nervous system, or does a seizure disorder exist?

*Hat der Impfling eine Erkrankung des Nervensystems durchgemacht oder besteht ein Krampfleiden?*

yes (*Ja*)

no (*Nein*)

3. Does the vaccinee have known allergies?

*Ist bei dem Impfling eine Allergie bekannt?*

yes (*Ja*)

no (*Nein*)

if so, which ones *wenn ja, welche?* \_\_\_\_\_

4. Did the vaccinee experience allergic reactions, 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*)

If you would like to know more about the vaccination against tetanus, diphtheria, whooping cough, Hib, polio, and hepatitis B, ask your vaccinating doctor!

*Falls Sie noch mehr über die Schutzimpfung gegen Wundstarrkrampf, Diphtherie, Keuchhusten, Hib-Erkrankungen, Kinderlähmung und Hepatitis B wissen wollen, fragen Sie den Impfarzt!*

Please bring your vaccination passport to the vaccination appointment!

*Zum Impftermin bringen Sie bitte das Impfbuch mit!*

**Consent***Einverständniserklärung***to vaccination against tetanus, diphtheria, whooping cough, Hib disease, polio and hepatitis B***zur Durchführung der Schutzimpfung gegen Wundstarrkrampf, Diphtherie, Keuchhusten, Hib-Erkrankungen, Kinderlähmung und Hepatitis B*

(Carbon copy forms are also available for vaccinees or their guardians to receive a copy in accordance with patient's right law)

*(Es stehen auch Formulare mit Durchschlag zur Verfügung, um den Impfungen bzw. ihren Sorgeberechtigten gemäß Patientenrechtegesetz eine Kopie mitgeben zu können.)*

Name of vaccinee \_\_\_\_\_

*Name des Impflings*

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

*geb. am*

I have read the information in this leaflet my doctor explained in detail the information about the vaccination in a meeting.

*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 agree to the suggested vaccination against tetanus, diphtheria, pertussis, Haemophilus influenzae type b, polio and hepatitis B.

*Ich willige in die vorgeschlagene Impfung gegen Wundstarrkrampf, Diphtherie, Keuchhusten, Haemophilus-influenzae-Typ-b-Erkrankungen, Kinderlähmung und Hepatitis B ein.*

I reject the vaccination. I was informed about possible disadvantages of rejecting this vaccination.

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

Comments: *Vermerke* \_\_\_\_\_Place and date: *Ort, Datum* \_\_\_\_\_\_\_\_\_\_  
Signature of vaccinee  
or legal guardian*Unterschrift des Impflings bzw. des Sorgeberechtigten*\_\_\_\_\_  
Signature of doctor*Unterschrift des Arztes/der Ärztin*