This information sheet in English is a non-binding translation of the information sheet in German. In the event of contradictions and/or ambiguities, the wording of the information sheet in German shall be applicable.

Information sheet

Vaccination against influenza with the tri-/tetravalent, cell-based inactivated vaccine Flucelvax® 2025/2026 season

! Important information: For the 2025/2026 flu vaccination season, only trivalent flu vaccines are available as recommended by STIKO (RKI).

The disease

Influenza is an infectious disease caused by viruses. There are three different types of influenza viruses: types A, B and C. However, only types A and B are currently relevant or dangerous to humans.
The influenza virus of serotype A can be divided into further subtypes based on the proteins in its envelope. Due to possible genetic changes in the envelope properties (especially in type A), the influenza virus presents a potential new challenge to the human immune system each time. Therefore, neither infection nor vaccination provides long-lasting immune protection.
Transmission can occur through droplet infection (e.g. sneezing, talking), direct contact (e.g. shaking hands) and contact infection via objects (e.g. door handles). The risk of infection is highest shortly before the onset of clinical symptoms and lasts for 3 to 5 days. The cells of the entire respiratory tract serve as a breeding ground for the virus during the acute infection, resulting in general symptoms and respiratory symptoms.
The first signs of illness appear within 24 to 48 hours after infection:

- High fever
- Severe feeling of illness
- Headache and muscle pain
- Respiratory symptoms (difficulty swallowing, dry cough, sore throat, inflammation of the trachea with pain behind the sternum)

The flu normally will heal up within 5 to 7 days. However, complications are often observed in people with pre-existing conditions, children and the elderly. The virus itself or a secondary bacterial infection can lead to pneumonia or inflammation of the heart muscle and/or pericardium, for example. Infants, young children, chronically ill patients and elderly people are particularly prone to hospitalisation, and many cases may prove fatal.
According to estimates, influenza caused by the influenza virus is responsible for 300,000 to 650,000 deaths worldwide each year. In Germany, it leads to 1-7 million visits to the doctor and an average of up to 10,000 deaths each year, particularly among the elderly and chronically ill. This makes influenza the disease with the highest population-related mortality rate. The economic damage caused by sick leave is also not to be neglected.

The treatment

Antiviral drugs can potentially be used for causal treatment of influenza if taken within the first 24 hours after the onset of symptoms. By inhibiting the replication of the virus in the cells, the course of the disease can be shortened and possible complications averted. However, there are increasing reports of resistance to these drugs. In addition, the disease is treated symptomatically as needed.

The prevention

An annual preventive vaccination with a flu vaccine recommended by the WHO and STIKO prevents infection or illness from the outset in most cases.

The benefits of vaccination

Vaccination with the trivalent/tetravalent vaccine protects against infection with both influenza A and influenza B subtypes. The effectiveness of the flu vaccine has been proven in numerous studies. The vaccine has been shown to provide 80-90% protection in immunocompetent individuals and to reduce the mortality rate by 48%. Within one year, a significant reduction in the risk of disease can thus be achieved in vaccinated individuals compared to unvaccinated individuals. Even unvaccinated contacts benefit from the protection afforded by vaccination, which is of benefit to the general public.
Vaccination during pregnancy also protects the newborn through the transfer of maternal antibodies.
With increasing age, the immune system's performance declines, infections can become more severe

and vaccinations less effective. STIKO therefore recommends that all persons aged 60 and over be given a vaccine with a higher antigen dose. Studies have shown that this high-dose vaccine is slightly more effective in older people.

The ingredients of the cell-based influenza vaccine Flucelvax®

Two types of inactivated influenza vaccines are available in Germany: vaccines produced in incubated chicken eggs and the influenza vaccine Flucelvax®, which is produced in cell cultures. Both types of vaccine can be used here in standard doses for all persons with the corresponding vaccination recommendation.

Among the chicken egg-based vaccines, both a high-dose vaccine containing four times the amount of viral surface antigens and a vaccine with an adjuvant are approved for older people. As the immune system's performance declines with age, infections are often more severe, and vaccinations may be less effective. For this reason, STIKO recommends that all persons aged 60 and over be vaccinated with a high-dose vaccine.

The inactivated, tri-/tetravalent vaccine contains surface antigens (virus envelope proteins without other virus components) from two subtypes of the influenza A virus and two subtypes (tetravalent vaccine) or one subtype (trivalent vaccine) of the influenza B virus strains.

The virus variants contained in seasonal vaccines are adapted annually to the current, globally expected infection situation due to the changing spread of the various influenza strains and their continuous mutation. Accordingly, the WHO issues a new recommendation for the vaccine composition each year.

Flucelvax® also contains sodium chloride, potassium chloride, magnesium chloride hexahydrate, disodium phosphate dihydrate and potassium dihydrogen phosphate.

The procedure and behaviour after vaccination

The vaccination is administered as a single dose and should be given shortly before the start of the annual flu season. The vaccine is mainly injected into the upper arm muscle.

No special precautions are necessary after vaccination, but excessive muscular strain on the injection site, unusual physical exertion and activities that increase the heart rate (e.g. saunas) should be avoided for 3 days after vaccination.

Who should be vaccinated against influenza

Annual vaccination is recommended primarily for people with an increased risk of transmission and/or disease but is also available to anyone who wants to take preventive measures to avoid the disease.

For the following group of people, there is a specific recommendation:

- All persons aged 60 and older (vaccination with high-dose vaccine)
- Persons aged 6 months and older with underlying conditions (respiratory tract, cardiovascular system, kidneys, metabolism, immune system, blood)
- Persons who frequently deal with the public
- People working in medical and nursing fields
- Persons who care for vulnerable persons
- Residents of retirement or nursing homes
- All pregnant women from the second trimester onwards, or from the first trimester onwards if they have an underlying condition that puts them at increased health risk
- Travelers aged 60 and older (high-dose vaccine) or those who are at risk due to an underlying condition, or in special travel circumstances (e.g. group travel, Hajj travel)
- Persons at increased risk due to frequent, regular and direct contact with certain animals (e.g. pigs, poultry, wild birds – wild or domesticated – and seals)

Who should not be vaccinated against influenza

People with known hypersensitivity to vaccine components (e.g. chicken egg protein allergy, known allergy to neomycin or other aminoglycoside antibiotics, formaldehyde) should not be vaccinated against influenza, or only after very careful consideration.

In such cases, the chicken egg protein-free vaccine Flucelvax® can be used.

Individuals who have experienced severe side effects following previous influenza vaccinations should refrain from receiving the flu vaccine until the cause has been definitively determined. Individuals with acute, high-fever infections should only be vaccinated after recovery.

In the case of autoimmune diseases, no connection has been found between seasonal influenza vaccination and the occurrence of disease flare-ups (e.g. multiple sclerosis, rheumatoid arthritis, systemic lupus erythematosus). Even if the possibility of triggering a flare-up cannot be ruled out with certainty, this risk is

probably significantly higher in the case of natural infection.
You must not receive Flucelvax® if you are allergic to:

- the active substances or any of the other ingredients of this medicine
- beta-propiolactone, cetyltrimethylammonium bromide or polysorbate 80

Possible side effects or complications following influenza vaccination with the cell-based vaccine Flucelvax®

The frequencies of side effects (as a percentage of those treated) are defined as follows: Very common (more than 10%); Common (more than 1%); Uncommon (more than 0.1%); Rare (more than 0.01%); Very rare (less than 0.01%). According to studies, the following side effects may occur in connection with vaccination:

Adults (aged 18 years and older):
Very common: headache (people up to 65 years of age), myalgia (muscle pain; people up to 65 years of age), pain at the injection site, fatigue, erythema (skin redness), induration (hardening)

Common: headache (65 years and older), myalgia (muscle pain; 65 years and older), loss of appetite, nausea, vomiting (persons up to 65 years of age), diarrhea, arthralgia (joint pain), ecchymosis (small skin haemorrhages), chills

Occasional: fever above 38°C, vomiting (65 years and older)

Side effects reported after market launch:
Allergic or immediate hypersensitivity reactions, including anaphylactic shock, paraesthesia (abnormal skin sensation), generalised skin reactions, including pruritus (itching), urticaria (hives) or non-specific exanthema (skin rash), swelling at the vaccinated limb

Children and adolescents aged 6 to 17 years:
Very common: headache, myalgia (muscle pain), pain / erythema (skin redness) / induration (hardening) at the injection site, fatigue

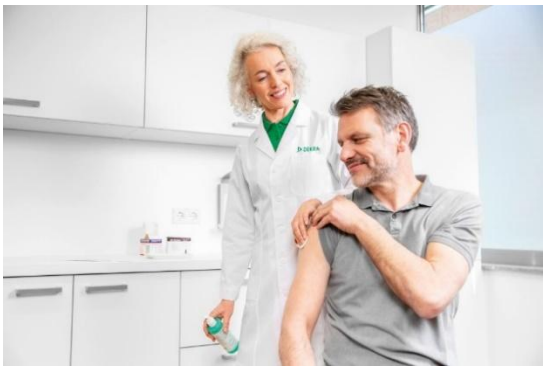
Common: loss of appetite, diarrhea, nausea, vomiting, arthralgia (joint pain), ecchymosis (small area of skin bleeding) at the injection site, chills, fever ≥ 38°C

Refresher interval

Due to the continuous mutation of the pathogens, the composition of the recommended vaccines changes. In addition, the vaccine does not provide lasting immunity. A booster for both the standard and high-dose influenza vaccines is recommended once a year during the season.
No further influenza vaccinations should be given within an influenza season. The high-dose vaccine is only slightly superior to the standard vaccine in terms of efficacy. Therefore, even after vaccination with the standard vaccine, sufficient protection can be assumed from the age of 60 onwards.

If you have any further questions, please contact your attending medical staff directly.

Vaccinations - General information



Vaccines are among the safest medicines. Most vaccinations are administered without complications and do not cause any health problems. Nevertheless, as with any medicine, vaccines can also have side effects.

Common reactions to vaccinations

Common reactions after vaccination include pain at the injection site, redness, fever and malaise. These symptoms often occur in the first few days after vaccination and are a sign that the body is responding to the vaccine. This activates the body's own immune defence system, producing antibodies and immune cells. Even if these reactions do not occur, the vaccination can still be effective.

Information on side effects

Your vaccination documentation contains special information sheets that inform you about the side effects and their frequency in relation to the vaccine used. In addition, the Infection Protection Act requires the following general information on protective vaccinations (§ 22).

What to do in case of unusual reactions to vaccination

A vaccination complication occurs when the side effects of a vaccination exceed the usual extent of a vaccination reaction. If you notice any unusual symptoms after a vaccination or suspect a vaccination complication, contact your doctor's office immediately. It is important to clarify whether the vaccination is the cause or whether other illnesses or interactions with medications are present.

Reporting of adverse drug reactions (vaccination complications)

If no other cause for the symptoms, which are atypical for a vaccine reaction, can be found, it may be a vaccine complication. In this case, doctors are obliged to inform the health authority. You also have the option of reporting the suspected case online via the reporting portal of the Federal Institute for Drugs and Medical Devices (PEI Paul-Ehrlich-Institut):
https://nebenwirkungen.bund.de
These reports are important in order to enable compensation claims, discover unknown risks and better assess known risks.

Care in the event of vaccine damage in accordance with §§ 60 to 64 of the Infection Protection Act (Infektionsschutzgesetz (IfSG))

According to the law, vaccine damage is 'the health and economic consequences of damage to health caused by vaccination that exceeds the usual extent' (§ 2). The determination of vaccine damage is the responsibility of the pension offices of the federal states. If vaccine damage is not recognised, it is possible to take legal action before the social court. State compensation is paid regardless of any manufacturer or treatment liability.