

Before administering the vaccination, the following information is additionally requested:

1. Are you/is the person to be vaccinated currently healthy?
2. Do you/does the person to be vaccinated have any known allergies (especially to chicken egg)? If yes, which?
3. Did you/the person to be vaccinated experience any allergic reactions, high fever or other unusual reactions after a previous vaccination?

## Information

### Influenza (4-valent) No. 11a

#### on protective vaccination against influenza ("flu") with 4-valent vaccine (tetraivalent vaccine)

Acute infections of the respiratory tract belong to the most common disorders. They are caused by a number of different pathogens, particularly by viruses. The influenza virus, the pathogen causing the 'genuine' flu that occurs every year in form of an epidemic, plays a special role. Compared to other pathogens of acute respiratory diseases, influenza viruses usually result in a more severe disease course.

The best protection consists of a timely performed vaccination. The influenza vaccination does not protect from other usually mild acute respiratory tract disorders caused by different pathogens.

Influenza is an acute disease involving fever, cough and muscle pain which, from a merely clinical point of view, cannot always be distinguished from other disorders of the respiratory tract. A sudden onset out of complete health is typical. Mainly in people over 60 years of age, chronically ill people and also pregnant women, severe courses are often observed. The viral flu occurs more frequently during the cold season. For this reason, people should generally be vaccinated in the autumn months (preferably in October / November). However, protective vaccination may be performed at any time.

#### Vaccines

As the influenza viruses are permanently changing, the influenza vaccination has to be repeated every year with an up-to-date vaccine. The so-called seasonal influenza vaccines are manufactured on an annual basis according to the actual WHO (World Health Organization) recommendations. These recommendations take account of the globally circulating influenza virus types A and B. The vaccine is effective against two influenza A viruses (A/H1N1 and A/H3N2) and two influenza B viruses. Although one of the influenza B lineages (Yamagata lineage) appears to have been eliminated according to WHO information, the vaccine virus is still contained in the vaccines available here for the 2024/2025 season. Even if the vaccine composition exceptionally remains unchanged in one season, the vaccine's

immune protection should be refreshed, as it lasts no more than 1 year.

The here discussed 4-valent vaccines against influenza are manufactured from chicken eggs. They are approved for adults and adolescents, even though – depending on the vaccine used – also children from 6 months of age may be vaccinated. The vaccine (0.5 mL) is preferably injected into the muscle (upper arm, lateral thigh), in individual cases also under the skin.

The influenza vaccination can be given together with other vaccinations, this also applies to COVID-19 vaccines. As a rule, the tolerability remains unaffected. Your vaccinating doctor can give you advise on this. Vaccinal immune protection becomes effective about 2 to 3 weeks after vaccination. Children up to 9 years of age who have never been vaccinated against influenza should receive a 2<sup>nd</sup> vaccine dose after 4 weeks at the earliest.

#### Who should be vaccinated?

The influenza vaccination is recommended to all persons being at particular risk from influenza:

- Persons aged 60 and older
- All pregnant women from the 2<sup>nd</sup> trimester of pregnancy (women exposed to increased health risks due to an underlying disease already from the 1<sup>st</sup> trimester)
- Those who are in frequent contact with many people due to their profession, such as bus drivers or teachers
- Residents of nursing or rest homes
- Adults, adolescents and children exposed to increased health risks due to an underlying disease, such as chronic respiratory tract disorders, chronic cardiovascular, liver and kidney diseases, metabolic disorders (such as diabetes), congenital and acquired disorders of the immune system (such as HIV infection), chronic neurological diseases (such as multiple sclerosis)
- Persons who may infect exposed individuals under their care, but who are at the same time at high risk of getting infected themselves by patients and persons needing care; this includes, for example, medical staff and those caring for old and sick people as well as any household members of the risk person
- Persons who are in direct contact with poultry and wild birds.

Pregnant women have a significantly increased risk of serious complications. However, the influenza vaccination not only protects the pregnant woman, but also indirectly protects the unborn or newborn child in the first weeks of life (nest protection). Adverse side effects have been observed neither in the mother nor in the child. Vaccination may be administered even during the breastfeeding period.

People of all ages with chronic neurological diseases, such as neuromuscular diseases, also have an increased risk of a severe disease course; this also applies to MS patients, in whom influenza can lead to exacerbations.

#### Who should not be vaccinated?

People affected by an acute disease (especially in case of febrile infections) should not be vaccinated. Vaccination is to be caught up at the earliest possible opportunity.

Individuals with a severe hypersensitivity to any vaccine components may not be vaccinated with this specific vaccine. For example, this may be the case if a person has a known severe allergy to chicken egg.

#### How to behave before and after vaccination?

Any tendencies to circulatory reactions or known immediate allergies should be reported to the doctor before vaccination. Fainting spells sometimes occur (as a stress reaction after or even before the puncture with the injection needle), which may be temporarily accompanied by impaired vision, discomfort or involuntary movements during the recovery phase.

Vaccinated persons do not need to take special care, but extraordinary and strong physical exertion should be avoided within 3 days of vaccination.

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

The vaccination may commonly to very commonly (in 1 to 10 percent or more) cause redness or painful swelling at the vaccination site. This reflects the body's normal way of dealing with the vaccine and mostly occurs within 1 to 3 days, rarely lasting very long. Swelling of nearby lymph nodes may occur, frequent itching, hardening or occasional haematomas ("bruising") may occur at the injection site.

The vaccinated persons may experience also general symptoms (in 1 to 10 percent or more) such as shiver, fever, gastro-intestinal symptoms like nausea, vomiting or diarrhoea, discomfort, exhaustion, fatigue, sleepiness, dizziness, sweating, headache, muscle and joint pain, occasionally also rash. In children, irritability and loss of appetite are also observed.

Normally, the above described local and general reactions are of a temporary nature and subside quickly without any lasting effects.

#### What about postvaccinal complications?

Postvaccinal complications are very rare adverse effects beyond the normal extent of a vaccination reaction, which significantly affect the vaccine recipient's health status. An influenza vaccination very rarely leads to allergic reactions, e.g., of the skin (such as rash, itching, hives or swelling of the skin, e.g. on the face) and respiratory tract. Allergic immediate reactions up to anaphylactic shock were reported in isolated cases only. Very rare complications are blood vessel inflammations (very rarely with renal involvement) or a temporary reduction of the platelet count which may result in bleeding events. Likewise, neurological side effects being temporally associated with the vaccination (e.g. discomfort, nerve inflammation, usually temporary paralysis, seizures with and without fever) have only very rarely been described in the medical literature.

#### Advice on possible side effects by the vaccinating doctor

In addition to this information leaflet, your doctor will offer you an explanatory consultation.

If after a vaccination you experience any symptoms beyond the rapidly subsiding local and general reactions described above, the vaccinating doctor will also be there to advise you.



Editor and ©: Deutsches Grünes Kreuz e. V., Marburg  
(according to the actual STIKO recommendations)

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ID 2024-08

If you want to know even more about the protective vaccination against influenza ("flu") with 4-valent vaccine, please ask the vaccinating doctor!