

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 (adjuvanted) No. 11e

on protective vaccination against influenza ("flu") with adjuvanted vaccine (persons aged 60 and older)

Acute infections of the airways are among the most common diseases. They are caused by a variety of pathogens, especially viruses. A special role is played by the influenza virus, the pathogen causing the 'real' flu, which can occur epidemically every year. 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.

Vaccine

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 adjuvanted vaccine discussed here (Fluad®) is effective against two different influenza A viruses and one influenza B virus. Even if the vaccine composition exceptionally remains unchanged in one season, the vaccine's

immune protection should be refreshed, as it lasts for 1 year at most. The vaccine is adjuvanted, i.e. it contains an adjuvant that enhances its effect, and is approved for the vaccination of adults aged 50 and older to protect against influenza virus disease. It is manufactured on the basis of chicken eggs and should always be injected into the muscle (usually the upper arm muscle, or the lateral thigh muscle, where appropriate).

The influenza vaccination can be given together with other vaccinations, this also applies to COVID-19 vaccines. In this case, one vaccination should be performed on the right upper arm, one on the left. In this case, individual vaccination reactions may be more severe. Your vaccinating doctor or the pharmacist can advise you on this. After vaccination, it takes 10 to 14 days for the vaccine to provide full protection.

Who should be vaccinated?

People aged 60 and over are particularly at risk from influenza. The risk of infection and a severe course of influenza increases again with an underlying disease or job-related activity. For persons aged 60 and over, the Standing Committee on Vaccination (STIKO) recommends an influenza vaccination with the adjuvanted vaccine discussed here or the high-dose vaccine. According to the STIKO recommendation, both vaccines offer better protection than conventional influenza vaccines for people in the 60-plus age group.

Who should not be vaccinated?

People affected by an acute disease (especially in case of febrile infections) should be vaccinated only after recovery.

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 protein. Since no data are currently available on this, pregnant individuals must not be vaccinated with the adjuvanted vaccine.

How to behave before and after vaccination?

If persons are prone to circulatory reactions or have known immediate allergies, the doctor or pharmacist should be informed before the vaccination. Fainting spells sometimes occur as a stress reaction directly after (or even before) the puncture with the injection needle.

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

After the vaccination, pain or tenderness at the vaccination site may occur very commonly (in 10 percent or more of vaccinated persons). Muscle or joint pain, fatigue and headache are also described very commonly.

Redness, induration or bruising at the injection site, chills and fever (38°C and above) as well as gastrointestinal complaints (loss of appetite, nausea, diarrhoea) occur commonly (in 1 to less than 10 percent of vaccinated persons). Occasionally (0.1 to less than 1 percent), vomiting and lymph node swelling near the vaccination site are also possible.

Furthermore, vaccinated persons rarely report a cellulitis-like reaction at the vaccination site, muscle weakness, skin rash, itching, pain in a limb, feeling unwell or weak, as well as pronounced swelling of the vaccination arm, which may persist for more than 1 week.

The above-mentioned reactions reflect the body's normal way of dealing with the vaccine; they usually occur within the first 3 days after vaccination and usually subside within 3 days 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.

After influenza vaccination with the adjuvanted vaccine, allergic reactions, e.g. of the skin (itching, rash, hives) and respiratory tract as well as erythema multiforme (severe skin condition with fever and general symptoms), or an angioedema (swelling of the skin, especially on the face), may occur in rare cases. Allergic immediate reactions up to anaphylactic shock were reported in isolated cases only.

Very rarely, blood vessel inflammation (possibly with temporary kidney involvement) or a temporary reduction of the platelet count possibly resulting in bleeding events may occur. In likewise very rare cases, neurological side effects (such as unpleasant sensations, nerve pain and inflammation, usually temporary paralysis, seizure with and without fever) have been described in the medical literature in temporal connection with the influenza vaccination.

Advice on possible side effects

In addition to this information leaflet, your doctor or the pharmacist 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 or pharmacist will also be there to advise you.



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(according to the actual STIKO recommendations)

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If you want to know even more about the protective vaccination against influenza, please ask the vaccinating doctor or pharmacist!