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

1. Does the vaccine recipient have an acute disease?
2. Has the vaccine recipient any known allergies (especially to chicken egg)? If yes, which?
3. Did the vaccine recipient experience any allergic reactions, high fever or other unusual reactions after a previous vaccination?

**Information** **Influenza (high-dose) No. 11d**

## on protective vaccination against influenza ("flu") with high-dose vaccine for 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. 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 high-dose vaccine discussed here also contains the components of two influenza A viruses (A/H1N1 and A/H3N2) and two influenza B viruses, which can circulate at the same time. However, 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 high-dose vaccine is approved for the vaccination of adults aged 60 and older to protect against influenza virus disease. It is manufactured on the basis of chicken eggs and should preferably be injected into the muscle (upper arm, if necessary lateral thigh), in individual cases also under the skin. The vaccine should not be injected into the buttock region or areas where a major nerve cord might run.
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 can advise you on this. Vaccinal immune protection becomes effective about 2 to 3 weeks after vaccination.

### Who should be vaccinated?

The German Standing Committee on Vaccination (STIKO) recommends influenza vaccination, preferably with high-dose vaccine, for all persons aged 60 and older, as they are particularly at risk from influenza. The high-dose vaccine contains 4 times the amount of vaccine antigen compared to conventional influenza vaccines and offers better protection 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. Your doctor can give you respective advice.

### How to behave before and after vaccination?

Any tendencies to circulatory reactions or known immediate allergies should be reported to the doctor before vaccination. Occasional fainting spells are observed as a psychogenic reaction before or after the puncture with the injection needle.
Vaccinated person do not need to take special care, but extraordinary physical exertion should be avoided within 3 days of vaccination.

## Possible local and general reactions after the vaccination

After the vaccination, redness and pain at the vaccination site as well as discomfort may occur very frequently (in 10 percent or more of the vaccinated persons). Malaise, muscle pain and headaches may also occur very commonly. Swelling, induration and bruising at the injection site, as well as chills and fever (37.5 °C and above) are common (occurring in 1 to less than 10 percent of the vaccinated persons). Swelling of the lymph nodes near the vaccination site is possible. Occasionally (in 0.1 to less than 1 percent of those vaccinated), itching at the injection site, fatigue, muscle weakness, lethargy, cough, and pain in the throat and pharynx occur. Also occasionally reported are gastrointestinal symptoms (abdominal pain, nausea and vomiting, diarrhoea). Rarely (in less than 0.1 percent of the vaccinated persons), weakness or dizziness, joint and limb pain, skin rash, redness of the eyes, hot flush or night sweats are observed. Chest pain has been reported in isolated cases. In individual cases, respiratory complaints (such as cough, shortness of breath, tightness in the throat) or also chest pain have been reported.

The above-mentioned reactions reflects 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 high-dose vaccine, allergic reactions, e. g. of the skin (itching, rash, hives) of the respiratory tract, or an angioedema (swelling of the skin, especially on the face), may occur in rare cases. Allergic immediate reactions (anaphylactic shock) were reported in isolated cases only. Other rare complications are blood vessel inflammations or a temporary reduction of the platelet count which may result in bleeding events. In likewise very rare cases, neurological side effects (such as unpleasant sensations, nerve inflammation, 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 by the vaccinating doctor

In addition to this information leaflet, you can ask your doctor for 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.

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(according to the actual STIKO recommendations)
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