

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? 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 (cell culture) No. 11c

on protective vaccination against influenza ("flu") with cell culture based 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. Mainly in people over 60 years of age, chronically ill people and also pregnant women, severe courses are often observed. A sudden onset out of complete health is typical. 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 currently globally circulating influenza virus types A and B. The cell culture vaccine discussed here is effective against two influenza A viruses (A/H1N1 and A/H3N2) 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 no more than 1 year.

The influenza vaccine produced in cell culture is approved for use in all persons from 6 months of age and offers an alternative to the traditional chicken egg-based vaccines in cases of confirmed allergy to chicken egg protein. The vaccine (0.5 mL) is injected into the muscle, preferably at the upper arm; in young children at the lateral thigh. Children aged 6 months to 8 years inclusive who have never been vaccinated against influenza will be given a 2nd vaccination at least 4 weeks apart. The influenza vaccination can be given together with other vaccinations, this also applies to COVID-19 vaccines. Vaccinal immune protection becomes effective about 14 days from vaccination.

Who should be vaccinated?

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

- Persons aged 60 and older (with high-dose or adjuvanted vaccine, see information sheet no. 11d or 11e)
- All pregnant women from the 2nd trimester of pregnancy (women exposed to increased health risks due to an underlying disease already from the 1st trimester)
- Those who are in frequent contact with many people due to their profession, such as bus drivers or teaching staff
- Residents of nursing or rest homes
- Persons with increased health risks, e.g. due to chronic respiratory, cardiovascular, liver and kidney disease or metabolic disease (such as diabetes), those with immunodeficiency, HIV infection, chronic neurological disease (e.g. multiple sclerosis, neuromuscular disease); in case of severe overweight (BMI $\geq$ 30)
- Persons who may infect exposed unvaccinated 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 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 e.g. pigs, poultry, wild birds, seals.

Pregnant women have a significantly increased risk of serious complications. Adverse side effects have been observed neither in the mother nor in the child. Vaccination may be administered even during the breastfeeding period.

As influenza A viruses are increasingly being detected in animals, persons with frequent private or work-related contact, e.g. with pigs, poultry, wild birds or seals (livestock farming, animal parks, animal shelters, veterinary practices, slaughterhouses) should be vaccinated. The vaccination is not exclusively for the individual protection of the vaccinated person, but it can reduce double infections (influenza viruses from animals and seasonal viruses circulating here); this also contributes to population protection.

Who should not be vaccinated?

Anyone suffering from an acute illness (especially febrile infections) should not be vaccinated. The vaccination should be caught up at the earliest possible time.

Individuals with a severe hypersensitivity to any vaccine components may not be vaccinated with this specific 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 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.

The vaccinated person does 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 very commonly (in 10 percent or more of vaccinated persons) cause pain, redness and induration at the injection site; in children and adolescents also a haematoma ("bruise"). A more pronounced swelling of the vaccination arm has been described very rarely in adults. This reflects the body's normal way of dealing with the vaccine and mostly occurs within 1 to 3 days, rarely lasting very long. Fatigue is very common; children under 6 years of age show drowsiness or irritability, as well as changes in eating habits. Chills occur frequently in all age groups (1 to 10

percent), fever above 38°C occasionally in adults (0.1 to 1 percent), frequently in children from 6 years of age and adolescents, and very frequently in children under 6 years of age. Loss of appetite is common (adults) or very common (children from 6 years/adolescents). Gastrointestinal complaints (nausea, vomiting or diarrhoea) are common, diarrhoea is very common in children under 6 years of age. Adults as well as children aged 6 and over and adolescents very often report headache and muscle pain, often also joint pain. Normally, the above described local and general reactions are of a temporary nature and subside quickly without any lasting effects. Overall, the above-mentioned vaccination reactions were observed less frequently in vaccinated persons aged 65 and older, and more frequently in children.

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 a vaccination with influenza cell culture vaccine, allergic reactions of the skin (itching, hives, rash) are observed very rarely. Allergic immediate reactions culminating in anaphylactic shock were reported in isolated cases only. In the medical literature, neurological side effects such as a febrile seizure, discomfort or usually temporary paralysis were also observed just in isolated cases in a temporal relation with the vaccination. All of the complications mentioned have so far only been described in adults, but cannot be ruled out in children or adolescents either.

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