Information on protective vaccination against influenza ("flu") with a high-dose vaccine for individuals 60 years of age and older

(Status as of October 2021)

Acute infections of the airways are amongst the commonest illnesses and are caused by a number of different pathogens, in particular viruses. The influenza virus, the cause of the real "flu", plays a special role and can recur each year in epidemic form. Compared to other pathogens causing acute respiratory illnesses, influenza viruses cause a severe disease course in most cases. The best protection is timely vaccination. The influenza vaccine does not protect against the generally milder respiratory illnesses caused by other pathogens.
Influenza is an acute illness accompanied by fever, cough and muscle pains which cannot always be differentiated from other respiratory illnesses on purely clinical grounds. Onset is typically sudden, from a state of full normal health. Severe clinical courses are frequently observed particularly in people over the age of 60 years, in those with chronic illnesses and in pregnant women. Viral influenza is more frequent in cold times of the year. Vaccination should therefore generally be performed in the autumn months (optimally October / November). Protective vaccination may, however, be performed at any time.

Vaccine

The influenza viruses change frequently, so that the influenza vaccination must be repeated each year with a current vaccine. The so-called seasonal influenza vaccines are constructed each year following the current recommendations of the World Health Organisation (WHO). The recommendations take into account the types of influenza A and B viruses circulating in the world. The high-dose vaccine described herein also contains the constituents of two type-A influenza viruses (A/H1N1 and A/H3N2) and two type-B influenza viruses which can occur simultaneously. However, even if, as an exception, the vaccine constituents were not to change in a season, the vaccine should still be refreshed as it lasts at most for 1 year.
The high-dose vaccine is licensed for protective vaccination against influenza in adults 60 years of age and older. It is produced using hens' eggs and should preferably be injected intramuscularly (upper arm or lateral thigh) but can in individual cases be injected subcutaneously. The vaccine should not be injected in the vicinity of the buttocks or large nerves.

If this influenza vaccine is given along with other vaccines, then one vaccine should be given into the right upper arm, the other into the left. This may potentially strengthen the individual immune responses. The vaccinating doctor can advise you on this. The vaccine protection starts about 2 to 3 weeks after vaccination.

Who should be vaccinated?

The Standing Committee on Immunisation (STIKO) recommends that all individuals 60 years of age and older be vaccinated against influenza, preferably using a high-dose vaccine, since they are particularly at risk of becoming ill with influenza. The high-dose vaccine contains 4 times more vaccine antigens than traditional influenza vaccines and offers better protection to individuals in the 60-and-over age group.

Who should not be vaccinated?

Anybody suffering from an acute illness (especially a febrile infection) should only be vaccinated after recovery. Individuals suffering from severe hypersensitivity to its constituents must not be given this vaccine. This may be the case, for example, in individuals with a proven severe allergic reaction to hens' albumen (egg whites).

Behaviour before and after vaccination

The vaccinating doctor should be informed prior to vaccination if individuals are prone to circulatory reactions or are known to have immediate allergic reactions. Individuals may occasionally faint directly after (or even before) the vaccination as a stress response to the needle stick. The person being vaccinated does not need to take any special precautions for the first 3 days following vaccination, although unusual physical exertion should be avoided.

Possible local and generalised allergic reactions following vaccination

Following vaccination, reddening and local pain at the injection site, as well as general malaise, occur very frequently (in 10% or more of people being vaccinated). Muscle pains and headache are also very common. Commonly (1 to under 10% of vaccinated individuals) swelling, hardening and a bluish spot may develop at the injection site, and chills and fever (37.5 °C and higher) may also occur. Lymph node swelling in the vicinity of the vaccination site is possible. Occasionally (in 0.1 to under 1% of vaccinated individuals), there may be itchiness at the injection site and fatigue. These reactions generally develop within the first 3 days of vaccination and subside within another 3 days. Occasionally, muscle weakness and exhaustion are described, as well as gastrointestinal symptoms (nausea and vomiting, diarrhoea). Rarely (in less than 0.1% of vaccinated individuals) weakness or dizziness, joint and limb pains develop. In individual cases, respiratory symptoms (e.g. cough, shortness of breath, a feeling of constriction in the throat) or chest pain have been described.

The above-named local and general reactions are an expression of the body's normal reaction to the vaccine. As a rule, they are transient and subside rapidly and without any consequences.

Are vaccine-induced complications possible?

Vaccine-induced complications are very rare consequences which go beyond the normal extent of vaccine reactions, and which appreciably impair the health of the vaccinated individual. Following vaccination with the high-dose influenza vaccine, allergic reactions e.g. in the skin (itchiness, rash, hives) and airways are possible. Only in individual cases have responses beyond immediate allergic reactions up to shock been reported. Very rarely, blood vessel inflammation can occur, or the blood platelet count can diminish transiently, which may lead to haemorrhages. Likewise, neurological complications have only been very rarely described in medical literature (e.g. abnormal sensations, nerve inflammation, transient paralysis, seizures with or without fever) in connection with the vaccination.

Advice on possible side effects from the vaccinating doctor

In addition to this information leaflet, your vaccinating doctor will offer an advisory consultation. If symptoms occur after a vaccination which go beyond the transient local and general reactions described above, the vaccinating doctor will, of course, likewise be available for further advice.

You can reach the vaccinating doctor

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(following current STIKO recommendations)
Available under order No. 11d from:
DGK Beratung + Vertrieb GmbH
Biegenstraße 6, D - 35037 Marburg
Telephone: 06421 293-0, Telefax: 06421 293-1 87

Code number 2021-10

Protective vaccination against influenza – with high-dose vaccine

Schutzimpfung gegen Influenza – mit Hochdosis-Impfstoff

Name

Name

Prior to vaccination, please provide the following personal details:

Vor Durchführung der Impfung wird zusätzlich um folgende Angaben gebeten:

1. Is the person to be vaccinated currently healthy?

Yes No

1. Ist die zu impfende Person gegenwärtig gesund?

ja nein

2. Does the patient have a known allergy – particularly to hen's egg white (albumen)?

Yes No

If yes, to what

2. Ist bei der Patientin/ dem Patienten eine Allergie – insbesondere gegen Hühnereiweiß – bekannt?

ja nein

wenn ja, welche

3. Has the person to be vaccinated had allergic reactions, a high fever or other unusual reactions following a prior vaccination?

Yes No

3. Traten bei der zu impfenden Person nach einer früheren Impfung allergische Erscheinungen, hohes Fieber oder andere ungewöhnliche Reaktionen auf?

ja nein

If you would like to know more about protective vaccinations against influenza - with the high-dose vaccine – please ask the vaccinating doctor!

Please bring your vaccination passport to the vaccination appointment!

Falls Sie noch mehr über die Schutzimpfung gegen Influenza – mit Hochdosis-Impfstoff – wissen wollen, fragen Sie die Impfärztin / den Impfarzt!

Zum Impftermin bringen Sie bitte das Impfbuch mit!

Confirmation of consent

to perform protective vaccination against influenza – with high-dose vaccine

(Forms with carbon copy are also available in order to provide the person being vaccinated, or their legal representative, with a copy in accordance with the law relating to patient rights)

Einverständniserklärung

zur Durchführung der Schutzimpfung gegen Influenza - mit Hochdosis-Impfstoff

(Es stehen auch Formulare mit Durchschlag zur Verfügung, um der zu impfenden Person bzw. der gesetzlichen Vertretungsperson gemäß Patientenrechtegesetz eine Kopie mitgeben zu können.)

Name of the person to be vaccinated

Name der zu impfenden Person

born on

geb. am

I have taken note of the contents of the information leaflet and have also been advised extensively on the vaccination by my doctor.

I have no further questions.

I consent to the proposed vaccination against influenza – with the high-dose vaccine.

I decline the vaccination. I have been advised of the possible consequences of this rejection.

Ich habe den Inhalt des Merkblatts zur Kenntnis genommen und bin von meiner Ärztin / meinem Arzt im Gespräch ausführlich über die Impfung aufgeklärt worden.

Ich habe keine weiteren Fragen.

Ich willige in die vorgeschlagene Impfung gegen Influenza – mit Hochdosisimpfstoff – ein.

Ich lehne die Impfung ab. Über mögliche Nachteile der Ablehnung dieser Impfung wurde ich informiert.

Remarks:

Vermerke:

Place, Date:

Ort, Datum:

Signature of the person to be vaccinated
or their legal representative

Unterschrift der zu impfenden Person
bzw. der gesetzlichen Vertretungsperson

Signature of the doctor

Unterschrift der Ärztin/ des Arztes