

Safety and effectiveness of the flu vaccination

Safety of the seasonal flu vaccination

How is the safety of a flu vaccine tested?

Every flu vaccine requires approval before it can be used in Germany. The approval procedure for this is strictly regulated and very complex. Various studies must demonstrate the quality, efficacy and tolerability of the vaccine.

Even after the vaccine has been approved for the first time, further tests are carried out to obtain approval for the German vaccine market. This approval is ultimately given by the Paul Ehrlich Institute (PEI). The tolerability of the vaccines will also continue to be monitored and evaluated after approval, taking into account the reports of adverse reactions by the PEI.

What side effects can occur after the vaccination?

Vaccines are generally well tolerated. The safety of the flu vaccination has also been demonstrated in various studies for pregnant women and the unborn child.

Irrespective of the vaccine, general reactions such as a cold are observed in isolated cases (e. g. mild fever and muscle or limb pain, see Figure 1).

The symptoms usually disappear within a few days.



Figure 1: Vaccination reactions after the seasonal flu vaccination
Up to 9 in 100 vaccinated people show reactions similar to a cold after the flu vaccination.

As with other vaccinations, temporary redness, mild pain and swelling may occur at the injection site. These local reactions are more common in the high-dose vaccine recommended for people aged 60 or over.

For children and adolescents aged 2 to 17 years, there is also a vaccine, which is administered only as a nasal spray. The most common side effects observed here are a stuffy or runny nose.

What happens if severe side effects occur?

Severe side effects are very rare. If you experience any other side effects after the vaccination, in addition to the mild reactions described, you should inform your doctor. This development is then reported to the health authority, which forwards the information to the PEI. In addition, patients can also send a report directly via the Internet to the PEI or the Federal Institute for Medicinal Products and Medical Devices (BfArM) (www.nebenwirkungen.pei.de).

The reported suspected cases of vaccine side effects or complications are documented and evaluated. A possible risk associated with the vaccination can therefore be quickly identified and appropriate measures can be taken.

When should you not be vaccinated and what should be considered?

If you have an acute disease requiring treatment with a fever above 38.5 °C, you should get vaccinated at a later date.

Children and adolescents whose immune system is weakened, who suffer from severe asthma or who are infected with salicylates (e.g. acetylsalicylic acid) should not be vaccinated against flu with the nasal spray.

People who have an allergy to components of the vaccine should inform their doctor. In the case of a medically diagnosed severe allergy to chicken protein, which is very rare, the vaccination should be given in an environment where clinical monitoring and treatment after the vaccination are possible. A chicken protein-free (produced in cell cultures) flu vaccine is also available, which is suitable for allergy sufferers. Please talk to your doctor about this.

Effectiveness of the seasonal flu vaccination

How effective is the vaccination for adults?

A protective effect of up to 80% was observed in young adults when the vaccine was well-matched with the circulating flu viruses. Older people often have a limited immune response, so the vaccination is less reliable for them. In older adults, the average effectiveness is 41%. Therefore, vaccines with an adjuvant or high-dose vaccines have been developed for older people. The Standing Commission on Vaccination recommends that people aged 60 and over get vaccinated with a high-dose vaccine that is more effective than the standard vaccine in this age group.



Benefits of the flu vaccination

- ▶ Less severe flu and complications (e.g. pneumonia, cardiovascular damage)
- ▶ Fewer hospitalisations due to flu
- ▶ Protection of people in the surrounding area who cannot build up protection from the vaccine themselves (e.g. in the case of immunosuppression).

Why is it necessary to have a new vaccination every year?

An annual vaccination is important to protect against the most common flu virus in each flu season.

Flu viruses are quick-change artists – they constantly change their "appearance". The World Health Organization (WHO) monitors this change worldwide in order to assess which virus variants are likely to appear next winter. Based on this, four virus variants are recommended every year. The vaccine is adapted each year to these flu virus variants, which are expected to be the most common.

What factors influence its effectiveness?

The effectiveness of the flu vaccine depends on many different factors and varies from year to year. This is due, among other things, to the extent to which the virus variants contained in the vaccine correspond to the flu viruses that actually occur most frequently. Studies also suggest that the later the flu wave begins, the less effective the vaccine is, as the flu viruses have already been able to change in the meantime.

But the performance of the immune system also influences the protective effect of the vaccination: Older people and children in their first years of life have a weaker immune system, so the effect of the vaccination is lower. This also applies to people with underlying medical conditions or people taking medication that reduces the function of the immune system – for example, after an organ transplant.

If there is an indication for vaccination against both influenza and COVID-19, the simultaneous administration of both vaccines is possible.

For more information on the flu vaccination:

Federal Centre for Health Education (BZgA):

- ▶ <https://www.impfen-info.de/grippeimpfung/>

Robert Koch Institute (RKI):

- ▶ www.rki.de/influenza-impfung

Paul Ehrlich Institute (PEI):

- ▶ www.pei.de/influenza-impfstoffe

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