

Informative factsheet on vaccination with Pandemrix against the novel A/(H1N1) influenza

The respiratory illness caused by the novel pandemic influenza A/(H1N1) virus is often accompanied by the sudden onset of symptoms. The **most frequent symptoms** include **fever, cough, headache and muscle aches, fatigue and loss of appetite, mimicking those of the yearly seasonal flu**. Some persons have reported nausea, vomiting and diarrhoea. At present, the novel flu is, in the majority of cases, a self-limiting disease that is no more severe than the 'normal' seasonal flu. Chronic conditions such as respiratory illness, cardiovascular disease, diabetes or pregnancy may sharply increase the severity of the disease. Unlike with the seasonal flu, young persons are also seriously affected at a disproportionate rate.

The incubation period of the novel flu A/(H1N1) virus seems to be similar to that of the seasonal flu. People can infect others shortly (less than 24 hours) before they notice the first symptoms and from then on up to one week.

According to current knowledge, vaccination against seasonal influenza does not protect against the novel A/H1N1 influenza.

The Vaccine

Specific vaccines have been developed to protect against the novel influenza A/(H1N1) virus. The vaccines used are inactivated vaccines (inoculation with killed virus) against the pandemic virus strain. The licensing and use of vaccines against the novel A/(H1N1) influenza are based on decades of experience with seasonal flu vaccines as well as on clinical studies with 'mock-up' pandemic influenza vaccines containing the antigen of the avian H5N1 influenza virus.

These studies have shown that two flu shots build up a sufficient immune response.

In the meantime, clinical data on the use of the vaccine Pandemrix H1N1 in healthy adults and elderly persons as well as children between the ages of 6 and 35 months are also available. They prove a high protection rate even after a single dose. These observations are borne out by the results of clinical studies with other pandemic H1N1 vaccines. Against this background, the Paul-Ehrlich-Institut (PEI) and the Robert-Koch-Institut (RKI) currently recommend a single-shot vaccination with the adult dose for all age groups from the 10th birthday. For children from six months up to nine years, a single shot with half the adult dose is sufficient.

A special feature of the vaccine Pandemrix against the novel A/(H1N1) flu is the use of immune-boosting additives (adjuvants) on an oil-in-water basis. These additives boost the body's immune response and provide a broader range of protection in case of virus mutations.

Pregnant women are at a higher risk of having a severe course of illness if infected with the novel flu A/(H1N1). Therefore, the Standing Committee on Vaccination (*Ständige Impfkommission - STIKO*) recommends that pregnant women be vaccinated against the novel flu after an individual benefit-risk evaluation. For this purpose, the non-adjuvanted and thimerosal-free CSL H1N1 Pandemic Influenza Vaccine has been available since mid-December in addition to Pandemrix. In the meantime, an extensive body of experience from Sweden attests to the safety and tolerability of Pandemrix in pregnant women. Consequently, both vaccine variants are generally suited for the vaccination of pregnant women. Accordingly, the STIKO points out in its current recommendation that pregnant women may be vaccinated both with the adjuvanted and the non-adjuvanted vaccine.

Who should not be vaccinated with Pandemrix?

Vaccination should, in principle, be preceded by an individual benefit-risk evaluation. This applies particularly to chronically ill persons, children and pregnant women for whom only few or no data from clinical trials are as yet available.

Persons suffering from an acute **feverish illness** that requires medical attention should not be vaccinated. These persons should thereafter seek vaccination at the earliest possible date.

Persons with a history of allergy to chicken protein (egg and chicken protein, ovalbumin) or to trace quantities of residual substances (thimerosal, formaldehyde, gentamycin sulphate, sodium deoxycholate), should very carefully consider whether or not vaccination against swine flu should be sought. If they do opt for vaccination, it should only be carried out where the technical and medication requirements for immediate emergency treatment are fulfilled and the vaccinee will be under observation for at least one hour after vaccination. Persons with a history of anaphylactic (life-threatening) reactions to any of the vaccine ingredients should not be vaccinated.

Possible vaccination side effects (see also technical information "Pandemrix")

The vaccination is generally well tolerated. Due to the addition of immune boosters (adjuvants), however, local or general reactions are somewhat more likely than with seasonal flu vaccines. Reactions include:

Redness and painful swelling at the injection site as well as headache, fever, fatigue, joint and muscle pain. Frequently ($\geq 1/100$ to $< 1/10$ cases), swelling of lymph nodes, pruritus or hemorrhages at the injection site, more intense sweating, chills or flu-like symptoms can occur. Occasionally ($\geq 1/1,000$ to $< 1/100$ cases), general symptoms such as shivering, drowsiness, numbness of the hands and feet, somnolence, insomnia, nausea, eczema, vertigo, general malaise, vomiting or abdominal pain have been observed.

Side effects are often signs of the body's normal response to the vaccine. In most cases, the above-mentioned local and general reactions are only transient and resolve without sequelae. The PEI has received reports from observational studies indicating that Pandemrix has caused, in very rare instances, allergic reactions that can involve skin reactions, such as pruritus and redness. In rare instances, reactions as severe as a shock have occurred. Moreover, thrombocytopenia was reported in isolated instances. This is a transient reduction of the blood platelets that are vital for blood clotting, which can lead to bleeding. Very rarely, vasculitis and neurological illnesses, such as the Guillain-Barré syndrome, or other nervous lesions (such as nervous inflammations or nerve diseases), have been observed.

Questionnaire and declaration of consent to the vaccination against the novel A/(H1N1) influenza

The foregoing information contains the essential details about this vaccine-preventable disease, the vaccine itself, vaccination, vaccination reactions and possible post-vaccination complications.

Before proceeding with the vaccination, please answer the following questions:

1.) Do you feel well at present?

Yes no

2.) Do you have a known allergy?

Yes no

If yes, to what? _____

3.) Have you ever had allergic symptoms, high fever or other unusual reactions after a vaccination?

Yes no

If yes, which? _____

4. Are you pregnant?

Yes no

5. Are you taking any medication?

Yes no

If yes, which? _____

Declaration of consent

to the vaccination against the novel A/(H1N1) influenza

Name of vaccinee:

Date of birth:

I have read and understood this factsheet. I have also been made aware of the possibility of asking the vaccinating physician any further questions I might have.

I have no further questions

I did have further questions, but they have been answered

I consent to the proposed vaccination against the novel influenza A/(H1N1)

Notes:

Place, date: _____

Signature of vaccinee or guardian or Signature of the informing physician