

## Informative factsheet on vaccination against the novel A/(H1N1) influenza with CSL H1N1 Pandemic Influenza Vaccine

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, no more severe than the 'normal' seasonal flu and resolves spontaneously. 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

### Why pregnant women are at particular risk

The novel flu spreads through droplet infection (sneezing, coughing, talking or kissing); however, the viruses continue to be infectious for some time on hands or surfaces. Pregnant women are at a markedly higher risk of suffering serious infection. This is due to many pregnancy-related processes in the body that abet a more severe course of illness. For instance,

the lungs and circulation of the pregnant woman must also supply the unborn with oxygen and are therefore under greater strain. In pregnancy, moreover, the immune system is modified to prevent immune responses against the embryo. The risk of a severe course of infection increases as pregnancy progresses. The best protection against the novel flu ("swine flu") is vaccination.

### The vaccine: CSL H1N1 Pandemic Influenza Vaccine

Specific vaccines have been developed to protect against the novel influenza A/(H1N1) virus. As is common practice with influenza vaccines, inactivated vaccines are used that do not contain any viruses capable of reproduction (inoculation with killed virus particles). The composition of the CSL H1N1 Pandemic Influenza Vaccine is similar to that of seasonal **flu vaccines without immune boosters** (adjuvants). Unlike the seasonal vaccines, this vaccine only contains antigens of the novel flu strain. The vaccine comes as a single dose in a pre-filled syringe and therefore does **not contain any preservatives** (such as thimerosal). **This vaccine is exclusively intended for use in pregnant women.**

Data available so far suggest that a single vaccine dose is sufficient. A second dose can be administered based on a public recommendation for optimum vaccine use.

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 adjuvanted vaccine Pandemrix is also available in addition to CSL H1N1 Pandemic Influenza Vaccine. 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.

### When should vaccination take place?

The STIKO recommends vaccination preferably from the second trimester, since risk increases with the progress of pregnancy.

### How safe is the vaccination?

For ethical reasons, vaccine studies are not carried out in pregnant women. Available data on pregnant women vaccinated with seasonal flu vaccines without adjuvants do not indicate any adverse effects on the pregnancy or the unborn. Generally, pregnant women may also be vaccinated with an adjuvanted vaccine. The decision of whether to use an adjuvanted vaccine (usually Pandemrix), or the CSL H1N1 Pandemic Influenza Vaccine, should be taken after exhaustive medical consultation weighing the benefits and possible risks involved.

### Possible vaccination side effects

(see technical information CSL H1N1 Pandemic Influenza Vaccine)

The vaccine is well tolerated. Nevertheless, local and general reactions occur often to very often. These include redness and painful swelling at the injection site as well as headache, fever, chills, fatigue, joint and muscle pain, nausea and malaise. These side effects usually resolve without treatment within one or two days of immunisation. If they persist, you should contact your doctor.

Since the vaccine resembles the seasonal flu vaccine, the side effects are likely to be similar as well. In addition to the already mentioned side effects, the following symptoms can occur: occasionally ( $\geq 1/1,000$  and  $< 1/100$ ) eczema; rarely ( $\geq 1/10,000$  and  $< 1/1,000$ ) numbness, neuralgic pain, fits, transient reduction of blood platelets which can cause bleeding (thrombocytopenia), allergic reactions (in rare cases as severe as an anaphylactic shock); very rarely ( $< 1/10,000$ ) vascular inflammation and neurological disorders such as inflammatory diseases of the peripheral and central nervous system (such as Guillain-Barré syndrome).

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 transitory and resolve without sequelae. Rare and very rare side effects cannot be identified in clinical studies.

## Who should not be immunised with the vaccine?

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

Pregnant women may not be immunised with the vaccine if:

- they are oversensitive (allergic) to the active principle or another ingredient of CSL H1N1 Pandemic Influenza Vaccine, to eggs, chicken protein, ovalbumin, or the antibiotics neomycin and polymyxin.
- if they are suffering from a disease accompanied by high fever or an acute infection.

Vaccination should be postponed until the pregnant woman is healthy again.

## Questionnaire and declaration of consent to the vaccination

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 any known allergies?  
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 taking any medication?  
Yes  no   
If yes, which? \_\_\_\_\_

### Declaration of consent

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

**Name of the person to be vaccinated:**

**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:**

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**Place, Date:** \_\_\_\_\_

\_\_\_\_\_  
Signature of vaccinee or guardian

\_\_\_\_\_  
Signature of the informing physician