

Frequently asked questions about the Early Protection Programme's monovalent pandemic vaccine

How do vaccines work?

When a person is given a vaccine, the immune system (the body's natural defence system) will produce its own protection (antibodies) against the disease. It takes about two weeks for the body to produce this protection.

The monovalent pandemic influenza vaccine is not a live vaccine and therefore none of the ingredients can cause influenza.

Is the monovalent Pandemic Influenza vaccine safe?

The vaccine is approved for use in New Zealand and has been used widely throughout the world, particularly in Europe where the European Medicines Agency estimates that about 480,000 people have been vaccinated.

It was approved for use in New Zealand in January 2010 as a two-dose regime. For full immunity with this pandemic vaccine, two doses are required to be given at least three weeks apart.

Side-effects of this pandemic influenza vaccine are similar to those associated with seasonal influenza vaccines. Most common side-effects include swelling, redness or soreness at the injection site. Some people will also have fever, headache, tiredness and muscle aches as well. These side-effects are temporary - usually less than 72 hours.

All vaccines have a rare risk of causing immediate severe reactions (anaphylaxis) and rates for anaphylaxis following immunisation are estimated to be around one to three per million doses.

Is the monovalent Pandemic Influenza vaccine safe for children?

Celvapan[®] may be used in children from six months of age and over. Influenza vaccines are not given to infants under six months of age.

Although there is limited data from clinical studies for the use of the Celvapan[®] vaccine in children, there are no reasons to doubt the vaccine's

safety in children. It has been used for children in overseas pandemic immunisation programmes where the data raised no safety concerns.

The Ministry is offering Early Protection immunisation for children aged between six months to five years because a significant number of young children were hospitalised during the first wave of the pandemic in 2009, particularly those with chronic health conditions.

It is important that vaccinators give parents and guardians information both about the risk of influenza in their young child and about the limited safety information.

Parents can then make an informed choice.

How has the monovalent Pandemic Influenza vaccine been tested?

The monovalent Pandemic Influenza vaccine being given in the Early Protection Programme has been tested in clinical trials.

Clinical data for Celvapan® demonstrates that, after two doses in 408 adults (including the elderly) immune responses, measured by rises in antibodies, were similar to those observed with other seasonal influenza vaccines.

Preliminary clinical data indicates after the first dose of the vaccine in 101 children aged between nine years and 17 years, 51 children aged three to eight years and 52 children aged six months to three years, an adequate immune response was achieved.

The vaccine meets all three internationally accepted criteria for license of influenza vaccines and data indicates that an adequate immune response is achieved.

Experience from influenza vaccines over many years shows that achieving a good immune response is very likely to also give good protection against that particular influenza strain.

Influenza vaccines are usually effective within two weeks of having the immunisation.

Is it true that getting the influenza immunisation puts you at risk of getting influenza?

No. Influenza immunisation cannot cause influenza because the monovalent pandemic vaccine contains no live viruses.

The vaccine contains inactivated virus particles. It stimulates the immune system to make antibodies that protect against circulating influenza viruses.

Many other viruses are also present throughout the year, so people may catch a different respiratory infection with 'flu-like' symptoms around the same time they are immunised and can mistakenly presume it is the influenza vaccine.

The influenza vaccine is generally well tolerated. Some side-effects have been reported and usually disappear within one or two days without treatment.

What can I expect after getting the monovalent Pandemic Influenza vaccination?

You are likely to react to the vaccination in the same way you would to the seasonal influenza vaccination.

Most side effects are mild in nature, short term and similar to other influenza vaccines. Fewer side effects are seen after the second dose than the first dose.

The Pandemic Influenza H1N1 2009 (swine flu) vaccination is administered in two doses given three weeks apart.

The most common side-effect is injection site pain. Other common side effects include joint or muscle pain, chills, fatigue, malaise, redness, swelling or bruising at the injection site, increased sweating, headaches, dizziness.

However, these side-effects are short lasting, usually less than 72 hours.

All vaccines have a rare risk of immediate severe reactions (anaphylaxis) and rates for anaphylaxis post immunisation are estimated to be around one to three per million doses.

How long will it take for me to have protection with the monovalent Pandemic Influenza vaccine?

It takes up to 14 days to develop protection after you have been immunised.

What are the risk factors that mean I should have the monovalent Pandemic Influenza vaccine?

If you are a frontline healthcare worker or if you are or have any of the following conditions:

- are pregnant or planning to get pregnant
- have diabetes
- have severe asthma/lung disease
- are morbidly obese
- have a heart disease

- have active cancer or are under treatment
- have a poorly functioning immune system

Who is considered a frontline worker?

A frontline worker is someone who is likely to be coming into contact with people infected with influenza or the Pandemic Influenza H1N1 2009 (swine flu) virus.

Frontline healthcare workers are staff in general practice, emergency departments, intensive care units and those who may have direct contact with at-risk patients.

These workers are likely to be health workers as they are required to provide health services to the community. During a pandemic, frontline health workers will be carrying a bigger work load caring for people who are sick with the virus. They are at higher risk of coming into contact with people who have been infected and spreading the virus.

As such, immunising this group is vital for the continued delivery of health services to the community.

I'm pregnant, why am I at higher risk from Pandemic Influenza (swine flu)?

You are at higher risk because studies have shown that all pregnant women are at greater risk from complications associated with influenza illness, both from Pandemic Influenza and other influenza strains.

Furthermore influenza vaccination of pregnant women has been shown to decrease the incidence of influenza in their newborn babies.

Pregnant women with coexisting medical conditions such as asthma or diabetes are at even greater risk of severe influenza-related illness, with a three to four times higher risk of having severe influenza.

Maternal influenza infection has been associated with an increased risk of maternal hospitalisation, fetal malformations and other illnesses.

Influenza infection in young infants often prompts hospitalisation and can predispose infants to pneumonia or ear infections.

I'm pregnant, is the monovalent Pandemic Influenza vaccine safe for me and my baby?

If pregnant women are infected by pandemic influenza H1N1 2009, they appear to be considerably more likely to develop severe disease, require hospitalisation or die as a result of complications compared with women who are not pregnant. The infection may also put the fetus and the newborn at risk. This risk is greatest in the second and third trimesters of pregnancy¹.

For this reason, pandemic influenza immunisation is strongly recommended for women who will be pregnant during the influenza season. The influenza vaccine is normally given in the second and third trimesters but may be offered to women who will be in the first trimester when influenza is circulating.

Immunisation will be free in 2010 for pregnant women wishing to have the influenza vaccine, under both the Early Protection Programme and the Seasonal Influenza Programmes.

Celvapan[®] may be used in pregnant women.

There have been clinical trials that show the efficacy of Celvapan[®]. Although, as is the case with most trials, pregnant women were not included in the trials, there is no reason to think that the vaccine would not be as effective for women during pregnancy.

Because Celvapan[®] is a new vaccine there is no safety data specifically about use during pregnancy. However, previous influenza vaccines have been shown to be safe during pregnancy and Celvapan[®] has been used in pregnant women in other countries².

Pregnant women need to be informed of this information as part of the informed consent process.

I think I might have had Pandemic Influenza H1N1 2009 (swine flu) last year. Can/should I have the vaccine this year?

It is advised to get immunised annually for two reasons; because protection lessens over time; second, because influenza can be caused by different influenza viruses each year and you cannot be sure which strain you caught last year.

The monovalent pandemic influenza vaccine will offer protection against the pandemic strain of influenza. The seasonal influenza vaccine will also offer you protection from two other common strains of influenza that you may be exposed to.

¹ World Health Organisation advice: "A fatal outcome was recorded in 2–9% of hospitalized patients. Pregnant women have a 10 times higher likelihood of requiring admission to an ICU compared with the general population; 7–10% of all hospitalized cases are women in their second or third trimester of pregnancy." http://www.who.int/csr/disease/swineflu/meetings/sage_oct_2009/en/index.html

² Tamma PD, Ault KA, del Rio C, et al. Safety of influenza vaccination during pregnancy. *Am J Obstet Gyn.* 2009;201(6):547-552.2.

If you have had pandemic influenza last year, you can be safely immunised, however immunisation provides no additional benefit in those who have had their influenza laboratory confirmed to be the pandemic influenza H1N1 2009 (swine flu).

Most people who have had a flu-like illness do not know whether they have had the specific Pandemic Influenza H1N1 2009 (swine flu) influenza infection or some other strain. In the absence of a documented laboratory-confirmed diagnosis of Pandemic Influenza H1N1 2009 (swine flu) infection, you should get immunised.

I want to have the pandemic only influenza vaccine and then the seasonal influenza vaccine, is it safe to have both?

Yes, it is safe to have both vaccines.

Can I have only one of the pandemic vaccinations and then the seasonal influenza vaccination?

The pandemic influenza vaccine that is presently available is administered in two doses, three weeks apart. It is recommended you have both doses for the best protection.

There is no concern with then having the seasonal influenza vaccination following the vaccination for the pandemic influenza.

Having the seasonal influenza vaccine will offer the best protection against the other seasonal influenza strains.

If I had pandemic influenza (swine flu) last year and get the vaccination this year, will I get more reactions at the site of the vaccination?

No, you are not expected to get increased reactions.

Side-effects of this pandemic influenza vaccine are similar to those associated with seasonal influenza vaccines. Most common side-effects include swelling, redness or soreness at the injection site. Some people will also have fever, headache, tiredness and muscle aches as well. These side-effects are temporary - usually less than 72 hours.

If I have the monovalent pandemic influenza vaccine and then the seasonal influenza vaccine, will I get local irritation at the site of the vaccination?

No, it is not expected that you will get increased reactions.

You may experience pain, redness and swelling at the site of vaccination, but this should go away within 72 hours.

Does taking Tamiflu and being vaccinated improve my chances of escaping influenza? Or is vaccination enough?

Tamiflu or Relenza are antiviral medicines that may be used to treat an influenza infection if given early in the illness. They can shorten the length and severity of your illness. Antiviral drugs do not prevent you getting influenza in the first place.

Vaccination is likely to protect you from the prevalent strains of influenza that may be circulating in the community.

I want to have the early monovalent pandemic influenza vaccine but I'm not in the 'higher risk group'. Can I get it anyway?

If you are not at higher risk, you will not be eligible to receive the vaccine under the early protection programme. There are limited supplies of the vaccine and as such only those at risk will get Celvapan®.

You can protect yourself from pandemic influenza by getting the seasonal influenza vaccine that will also give you the added protection against two other seasonal influenza strains.

I have a young baby and/or I'm pregnant. Is it safe to have three influenza injections this year (two-dose pandemic influenza plus the seasonal vaccine) instead of just getting one as in other years?

International evidence on the safety of the influenza vaccine shows no evidence of harm to the fetus from immunisation of pregnant women using inactivated virus vaccines.

Both the United States Advisory Committee on Immunisation Practices (ACIP) and the Australian NHMRC recommend that pregnant women should be vaccinated before the influenza season, regardless of the stage of pregnancy.

The immunisation you receive from the pandemic influenza vaccine will not protect you from other seasonal influenza strains so it is recommended that you are immunised against seasonal influenza as well.

It is safe to have both vaccinations, two doses of the Early Protection Programme's monovalent vaccine and the seasonal flu vaccine.

Because Celvapan® is a new vaccine there are no safety data specifically about use during pregnancy. However, previous influenza vaccines have

been shown to be safe during pregnancy and Celvapan[®] has been used in pregnant women in other countries³.

Pregnant women need to be informed of this information as part of the informed consent process.

I've heard that many people over 65 are already immune to Pandemic Influenza H1N1 2009 (swine flu). Should I get the influenza vaccine this year?

Individuals 65 years and older are not expected to be at higher risk from Pandemic Influenza H1N1 2009 (swine flu) as they are likely to have some pre-existing immunity.

However they do remain at risk from seasonal influenza strains so it's recommended they have the seasonal influenza vaccine when it is available from their doctor or nurse.

For older people living in the community, influenza vaccine is associated with a 26 percent reduction in risk of hospitalisation for influenza or pneumonia and 42 percent reduction in the risk of death.

I'm worried about getting the vaccination. Who should I talk to for more advice?

Speak to your doctor or practice nurse if you have concerns about getting vaccinated or phone the immunisation advice line 0800 IMMUNE (466863).

What is informed consent?

The Ministry of Health recommends immunisation, however it is the patient's or their parent's/guardian's choice to accept immunisation.

Health professionals have legal obligations to obtain informed consent. The individual or guardian needs to understand the risks and benefits of vaccination, in order to give informed consent.

As part of the informed consent process the vaccinator should discuss with the individual or parent/guardian:

- what the risks are to them or their child if they contract pandemic influenza
- that the Celvapan[®] vaccine has been approved for use in New Zealand

³ Tamma PD, Ault KA, del Rio C, et al. Safety of influenza vaccination during pregnancy. Am J Obstet Gyn. 2009;201(6):547-552.2.

- there is limited information available on the use of the Celvapan® vaccine in pregnant women, children under 9 years of age and co-administration with other vaccines
- it is the individual's or parents/guardians choice whether to be immunised against pandemic influenza or not
- it is also the individual's or parents/guardians choice whether to vaccinate with the Celvapan vaccine or seasonal influenza vaccine
- that no identifiable information is being collected nationally about either the Celvapan® or seasonal influenza vaccines.