



Cervical cancer Vaccine



quick flipchart

Information on human papillomavirus (HPV) vaccine
for health professionals and young women

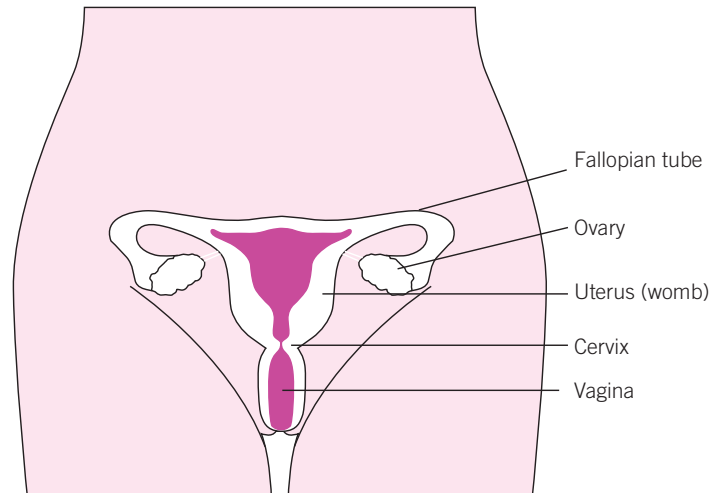


Contents

What is cervical cancer?	3
What causes cervical cancer?.....	4
How can the vaccine protect against cancer?.....	5
Why vaccinate?	5
Who is eligible for the free vaccine?	6
About the cervical cancer vaccine	8
How is the vaccine given?.....	9
When is it best given?	9
The National Immunisation Register (NIR).....	10
How safe is the vaccine?	11
How effective is GARDASIL®?	12
Should young women who have been vaccinated still have cervical smear tests when they are older?.....	13
Contraindications to GARDASIL®	15
Precautions.....	16
Immunisation Schedule.....	17
Proposed programme roll-out.....	18
Additional programme information.....	19
GARDASIL® vaccine contents.....	20
Alternative Immunisation Schedule.....	21

What is cervical cancer?

- Cervical cancer is cancer of the cervix.
- The cervix is the lower part of the uterus or womb and is at the top of the vagina.
- Cervical cancer develops when abnormal cells grow on the cervix.





What causes cervical cancer?

- Cervical cancer is caused by human papillomavirus (HPV), a very common virus passed on by sexual contact.
- Most people will come into contact with HPV at some stage during their lives. (About four out of five people will have HPV infection sometime).
- Most HPV infections clear by themselves, but some types can cause cell changes on the cervix that may lead to cervical cancer 10 to 20 years after infection.
- Other strains can cause genital warts but these strains do not lead to cancer.



How can the vaccine protect against cancer?

- The vaccine works by causing the body's immune system to produce its own protection (antibodies) against the HPV types that cause most cervical cancers.

Why vaccinate?

- More than 99% of cervical cancer is linked to infection with HPV.
- Every year in New Zealand about 160 women are diagnosed with cervical cancer and 60 die from it.
- Vaccinating girls and young women now against the main viruses that may cause cervical cancer will reduce their chances of getting cervical cancer later in life.
- In the long term more than 30 lives may be saved every year.



Who is eligible for the free vaccine?

- Girls born on or after 1 January 1990 are eligible for the free cervical cancer vaccine.
- From 1 September 2008 young women born in 1990 and 1991 will be eligible for the free vaccine through their family doctor, practice nurse or health clinic.
- From 2009, the cervical cancer vaccine will be added to the National Immunisation Schedule and offered to 12 year old girls (school year 8) on an ongoing basis. Girls up to 18 years of age will also be offered the vaccine. Most will receive it at school (see the table on page 18).



Who is eligible for the free vaccine?

- Girls or young women born on or after 1 January 1990, who have paid for the first or second doses before the programme started, can receive the remaining dose(s) free to complete the course.
- Non-resident girls under 16 will be eligible provided they are in New Zealand for eight months or more. No other non-resident girls are eligible.
- This government funded immunisation programme is not available to boys. This may be reconsidered later.

About the cervical cancer vaccine

- The vaccine being used in New Zealand is GARDASIL®. It protects against the two HPV types that cause 7 out of 10 cervical cancers (types 16 and 18) and the two HPV types (6 and 11) that cause 9 out of 10 cases of genital warts.
- The vaccine does not contain the HPV virus. It contains HPV virus-like particles of HPV types 16, 18, 6 and 11. These particles are proteins from the outer shell of the virus. They are a part of the virus and are not live and cannot cause infection. The particles cause the immune system to make antibodies against them.

For more detail on the vaccine contents please see the table on page 20.



How is the vaccine given?

- The vaccine is injected into the upper arm. Three injections are given over a 6-month period. The second dose is given 2 months after the first dose, followed by a third dose 4 months later (see page 21 for alternative schedules).

When is it best given?

- For best protection girls need to be vaccinated before exposure to HPV, which means before they start having any sexual contact.
- Eligible young women who are sexually active are recommended to have the vaccine as they may not have been exposed to all the HPV types the vaccine protects against.



The National Immunisation Register (NIR)

- HPV immunisations will be recorded on the NIR so that reminders can be issued if the course is incomplete. The information will also be used to check the impact of the vaccine programme on cervical cancer rates.
- Young women or their parent/guardian can choose not to have immunisation details recorded on the NIR but they can still receive the vaccine.



How safe is the vaccine?

- GARDASIL® was shown to have an excellent safety profile during large clinical trials involving more than 20,000 girls and young women.
- GARDASIL® has been licensed for use in more than 100 countries, including New Zealand, Australia, the United States, and the 27 countries in the European Union including the U.K.
- Monitoring of the vaccine is on-going.
- New Zealand's Centre for Adverse Reactions Monitoring will record any reactions reported after HPV vaccination.



How effective is the vaccine?

- Clinical trials of the vaccine found it was highly effective in preventing HPV infection (and the cellular changes that can lead to cancer) caused by the HPV types in the vaccine.
- Results from studies showed that after 3 doses of GARDASIL[®], antibodies to HPV persisted for at least 5 years. The vaccine was effective at preventing persistent infection with HPV in 96% of women.
- These studies will continue to monitor the protection the vaccine provides.
- Booster doses (as required for some other vaccines), are not expected to be needed for the cervical cancer vaccine, but this is being monitored.



Should young women who have been vaccinated still have cervical smear tests when they are older?

- Yes. About 30% of cervical cancers will not be prevented by the vaccine. As with any vaccine, GARDASIL® may not provide protection for everyone who is vaccinated. Therefore, if a woman has ever been sexually active, she still needs to have a smear test every three years between the ages of 20 and 70.
- The vaccine does not prevent about 10% of genital warts, nor will it prevent other sexually transmissible infections (STIs), or pregnancy.

Possible reactions to the GARDASIL[®] vaccine

	Type of reaction	What to do about reactions
Common expected reactions	<ul style="list-style-type: none"> – Swelling and pain at the injection site (hard and sore to touch at the injection site) – Heavy arm – Feeling nauseous or unwell – Dizziness – Headache 	<ul style="list-style-type: none"> – Place a cold, wet cloth or ice pack on the place where the injection was given. Leave it on for a short time. – Rubbing the arm will make these reactions worse. – Consider Paracetamol for the pain.
Other less common reactions	<ul style="list-style-type: none"> – A fever (feeling hot) – Vomiting – Fainting (light headedness) 	<ul style="list-style-type: none"> – Give extra fluids to drink. – Give Paracetamol to lower the fever if necessary. Follow the instructions on the packet.
Serious reactions	<ul style="list-style-type: none"> – Anaphylaxis 	<p>This is a serious allergic reaction that usually happens in the first few minutes after vaccination when a person is being observed. Treatment is available.</p>



Contraindications to GARDASIL®

The vaccine is **not** recommended for the following people:

- Anyone who has had a life-threatening reaction (hypersensitivity or anaphylaxis) to yeast or any other component of GARDASIL®
- Anyone who has had an anaphylactic reaction
- Pregnant women, because the vaccine has not been tested on them.



Precautions

- Giving GARDASIL® at the same time as other vaccines has not been studied in clinical trials (except for the hepatitis B vaccine). Therefore giving GARDASIL® at the same time as other vaccines is not recommended.
- People with severe illnesses should wait until they recover to receive their cervical cancer immunisation.

These people may receive the vaccine:

- Women who are breastfeeding may safely get the vaccine
- People with a mild illness can still get their immunisation as scheduled.

The National Immunisation Schedule*

Age	Diseases covered and Vaccines
6 weeks	Diphtheria/Tetanus/Whooping Cough/Polio/ Hepatitis B/ <i>Haemophilus influenzae</i> type b 1 injection (INFANRIX® -hexa) Pneumococcal 1 injection (Prevenar®)
3 months	Diphtheria/Tetanus/Whooping Cough/Polio/ Hepatitis B/ <i>Haemophilus influenzae</i> type b 1 injection (INFANRIX® -hexa) Pneumococcal 1 injection (Prevenar®)
5 months	Diphtheria/Tetanus/Whooping Cough/Polio/ Hepatitis B/ <i>Haemophilus influenzae</i> type b 1 injection (INFANRIX® -hexa) Pneumococcal - 1 injection (Prevenar®)
15 months	<i>Haemophilus influenzae</i> type b 1 injection (Hiberix™) Measles / Mumps / Rubella - 1 injection (M-M-R® II) Pneumococcal 1 injection (Prevenar®)
4 years	Diphtheria/Tetanus/Whooping Cough/Polio 1 injection (INFANRIX™-IPV) Measles/Mumps/Rubella 1 injection (M-M-R® II)
11 years	Diphtheria/Tetanus/Whooping Cough 1 injection (Boostrix™)
12 years girls only	Human Papillomavirus ** 3 doses given over 6 months (GARDASIL™)

* from 1 June 2008 ** from 2009

Proposed programme roll-out

(Information on the local programme will be available from the DHB)

Date	Year at school	Age Range	By birthdate	Delivery
1st September 2008*	n/a	17-18	1990	Primary care community-based settings only
	n/a	16-17	1991	
2009	8	11-13	1997	School-based programme begins, at the same time as the primary care and community-based programme settings continue ↓
	13	16-18	1992	
	12	15-17	1993	
2010	8	11-13	1998	
	12	15-17	1994	
	11	14-16	1995	
	10	13-15	1996	
2011 and onwards	8	11-13	1999	

*From 1 September 2008 the following girls may also receive the vaccine from primary care and community-based settings:

- Girls born from 1992 onwards who are not in school
- Eligible girls who paid for HPV vaccine dose 1 and/or 2 prior to 1 September 2008
- Eligible girls who may benefit from receiving HPV vaccine (eg because of risk)

Additional programme information

Vaccine ordering	Propharma: 0800 400 101
Cold chain	Your local immunisation coordinator or see the IMAC website www.immune.org.nz (go to the Health professionals page then select “Resources online” from the left hand index)
Immunisation benefit claiming	HealthPAC: 0800 458 448 http://www.moh.govt.nz/moh.nsf/indexmh/healthpac-claims-immunisation#faqs
Technical advice	IMAC: 0800 IMMUNE or 0800 466 863 www.immune.org.nz
Vaccine manufacturer	Merck Sharpe and Dohme – marketed in NZ by Commonwealth Serum Laboratories (CSL) Biotherapies Ltd (09) 579 8105 www.gardasil.co.nz
HPV Immunisation Programme	HPV Immunisation Programme queries: hpv@moh.govt.nz

GARDASIL[®] vaccine contents

Component	Function
Very small HPV 6, 11, 16 and 18 virus like particles from the outer shell of the virus	Antigen (causes the immune response)
Aluminium (as aluminium hydroxyphosphate sulphate)	Adjuvant to enhance immune response
Sodium chloride L-histidine Polysorbate 80 Sodium borate Water	Adjust tonicity Controls pH - stabiliser Surfactant - stabiliser Adjust pH - stabiliser For injection

For more information see the GARDASIL[®] datasheet on the Medsafe website:

<http://www.medsafe.govt.nz/profs/Datasheet/g/Gardasilinj.htm>

Alternative Immunisation Schedule

If an alternative schedule is required, the second dose should be given at least 1 month after the first dose, the third dose given at least 3 months after the second dose, and the course completed within one year.