

Continuous Professional Education Programme for Registered Nurses and Midwives to Administer Gardasil 9 Vaccine

**Under the Medicine Protocol to Girls
in Second Level Schools (or
equivalent) through a Schools
Immunisation Programme**

Medicine Protocol

This Medicine Protocol is a specific written instruction for the administration of Gardasil 9 Vaccine to students who may not be individually identified before presentation for vaccination.

Clinical Criteria

Active immunisation against and prevention of:

- Premalignant and malignant genital lesions (cervical, vulvar, vaginal, and anal) causally related to Human Papillomavirus (HPV) types 16,18,31,33,45,52,58.
- External genital warts (condyloma acuminata) causally related to HPV types 6 and 11

Circumstances in which the Medicine Protocol applies

- HPV immunisation programme will be delivered annually by the Health Service Executive (HSE) mainly via school based immunisation programme.
- All students in first year in second level schools or age equivalent (in special schools and home schooled), as recommended by NIAC in a 0, and 6 month schedule within the academic year for all aged < 15 years.
- <https://www.immunisation.ie/en/HealthcareProfessionals/ImmuneGuidelines/>

Circumstances in which the Medicine Protocol applies

For **2020/2021** Gardasil 9 will be given to :

- All **students** in first year, in second level schools and age equivalent in special schools and home schooled students including in a mop up clinic:
- Students who started with HPV9 schedule but did not complete in 2019/20 school year due to schools closures
- Also if schedule is delayed beyond recommended 6-13 months the course is still valid and does not need to be restarted.
- **There is no HPV9 vaccine catch up programme in 2020/21 school year.**

Interrupted Immunisation Schedule

- “If an immunisation course is interrupted, it should be resumed as soon as possible”.
- It is NOT necessary to repeat an interrupted immunisation schedule
- <https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/chapter2.pdf>

Inclusion Criteria for Gardasil 9

- Students in first year of second level school or age equivalent in special schools and home schooled students (NIAC, 2014).
- Students with valid consent.

Exclusion Criteria for Gardasil 9 Vaccine

- Any student who has had an anaphylactic or hypersensitivity reaction to a previous dose of Gardasil 9 or any of its constituents.
- Pregnancy.
- Contraindication to intramuscular injection
(haematological disorder/coagulation disorder)

Exclusion Criteria

- Acute febrile illness. The presence of a minor infection such as a mild upper respiratory infection or low grade fever is not a contraindication for immunisation.
- Students who are Immunocompromised either due to disease or treatment.

Gardasil 9 Vaccine: Product Information

- Details of the most current and update information of the SmPC and other data is available on the website <https://www.hpra.ie>

Possible Side Effects – Gardasil 9

- **Very Common:** (more than 1 per 10 doses of vaccine)
Pain, swelling and redness at injection site
Headache
- **Common:** (more than 1 in 100 doses and less than 1 in 10 doses)
- Itching and bruising at the injection site
- Dizziness
- Fever
- Nausea
- Fatigue

- Allergic reactions have also been reported. Some of these reactions have been severe. Symptoms may include difficulty breathing, wheezing, hives and/or rash.
 - For a full list of side effects refer to [https:// www.hpra.ie](https://www.hpra.ie)

Gardasil 9 Constituents

Antigen: L1 virus like particles for HPV Type 16,18, 31,33,45,52,58

Adjuvant: aluminium hydroxyphosphate sulphate adjuvant
(0.5 milligrams Al)

Excipients:

- Sodium chloride
- L-histidine
- Polysorbate 80
- Sodium borate
- Water for injection

Nature and Contents of Pack- Gardasil 9

- Gardasil 9 is only available in single packs of pre-filled syringes ready for use for intramuscular injection
- Vaccine contains two needles –
- 23G x 25mm – should be used,
- Prior to agitation, Gardasil9 may appear as a clear liquid with a white precipitate.
- After thorough agitation, it is a white, cloudy liquid

Frequency of Administration

- The person to be vaccinated will receive 2 or 3 individual doses of the vaccine. All 2 or 3 doses should aim to be given within a 12-month period.
- For those who commence vaccine under 15 year of age
- 1st dose: 0 month (Sept- Nov)
- 2nd dose: 6 months (Feb-May) after first injection
- The second dose can be given least five, but ideally six months after the first dose. NIAC recommends that “two doses should ideally be separated by 6 to 12 months. The minimum interval between doses is 5 calendar months”. The 4 day rule applies.

Frequency of Administration- Those aged 15 years +

- Students aged 15 years and older at time of first HPV vaccine (Gardasil 9) require 3 doses of HPV vaccine.
- The minimum interval between the first and second doses is 4 weeks.
- The minimum interval between the second and third doses is 12 weeks.
- **However** the minimum interval between the first and third doses is 5 calendar months.

Any Questions