

Continuous Professional Education Programme for Registered Nurses and Midwives to Administer

Gardasil (HPV4) 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 (HPV4) Vaccine** to girls who may not be individually identified before presentation for vaccination.

Clinical Criteria

Active immunisation against and prevention of:

- Premalignant genital lesions (cervical, vulvar and vaginal).
- Cervical cancer causally related to Human Papillomavirus (HPV) types 16 and 18.
- External genital warts (condyloma acuminata) causally related to HPV types 6 and 11.

Circumstances in which the Medicine

For 2020/2021 **Gardasil** (HPV4) will be given to :

- All girls who commenced the HPV vaccine schedule during the 2019/2020 school year to complete the schedule.

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 (HPV4) Vaccine

- 1. All girls in second level schools and or age equivalent in special schools and home schooled who commenced the HPV vaccine schedule during the 2019/2020 school year to complete the schedule.

Exclusion Criteria for Gardasil (HPV4) Vaccine

- Any girl who has had an anaphylactic or hypersensitivity reaction to a previous dose of Gardasil 4 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
- Girls who are immunocompromised either due to disease or treatment

Gardasil (HPV4) 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 (HPV4)

- **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
 - Pain in extremity
 - Fever
 - Nausea
 - **Rare:** (more than 1 in 10,000 doses and less than 1 in 1000))
 - Urticaria (Hives)
 - **Very Rare:** Bronchospasm (wheeze)
- **For a full list of side effects refer to SmPC at**
<https://www.hpra.ie>

Gardasil 4 Constituents

- Virus: HPV Type 6 L1 protein (20 micrograms)
HPV Type 11 L1 protein (40 micrograms)
HPV Type 16 L1 protein (40 micrograms)
HPV Type 18 L1 protein (20 micrograms)
- **Other Constituents:**
Sodium chloride; L-histidine; Polysorbate 80;
Sodium borate; Water for injection;
Adjuvant used is Amorphous Aluminium hydroxphosphate sulphate

Gardasil (HPV4) is cultured in yeast but there is no yeast in the final product.

Nature and Contents of Pack- Gardasil (HPV4)

- Gardasil (HPV4) 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,
 - 25G x 16mm
- Prior to agitation, Gardasil (HPV4) 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.
- Girls aged under 15 years of age when they commence the programme require a second dose after at least six months as per NIAC guidelines
- NIAC “recommends that the minimum interval between HPV1 and HPV2 is 24 weeks and the 4 day rule applies.
- This means the second dose of HPV vaccine can be considered valid if given at an interval of 24 weeks - 4 days after the first dose”

Frequency of Administration- Girls who start vaccine aged 15+

- Girls who start HPV vaccine aged 15 years of older require three doses of vaccine
- These girls may be given dose 1 and 2 as part of the routine school programme i.e. at 0 and 6 months and a third dose should be given at least three months and preferably four months after the second dose.
- Doses administered at 0, 1 and 6 months are recommended, however if flexibility in the schedule is necessary, the second dose can be administered at 1-2.5 months, and the third dose at 5-12 months after the first dose.

HPV 4 or HPV 9?

- Girls still in school but older than first year are eligible to receive HPV4 to complete a course already started or to commence a course not stated because of Pandemic.
- If HPV4 stocks are no longer available they may complete their HPV course using HPV9. The HPV vaccine course does not need to be repeated.

Any Questions?