



Seirbhís Sláinte

Building a **Better Health**

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
- <u>https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/chapt</u>
 <u>er2.pdf</u>

Inclusion Criteria for Gardasil (HPV4) Vaccine

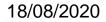
 1. All girls in second level schools and or age equivalent in special schools and home schooled who commenced the HPV vaccine schedule during the 2019/2020 school year to complete the schedule.

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)

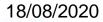
Exclusion Criteria

- 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



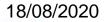
Gardasil (HPV4) Vaccine: Product Information

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



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

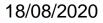
Gardasil (HPV4) is cultured in yeast but there is no yeast in the final product.

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.

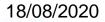
Frequency of Administration

- The person to be vaccinated will receive 2 or 3 individual doses of the vaccine.
- Girls aged <u>under 15 years</u> 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?

