

Human papillomavirus vaccine

Gardasil[®]9—Clinical advice for GPs

To support the introduction of *Gardasil*[®]9 in a two-dose schedule under the school-based National Immunisation Program (NIP) from January 2018



HPV
Vaccine

From January 2018, the 9-valent HPV vaccine *Gardasil*[®]9 (two-dose schedule) will replace the 4-valent HPV vaccine *Gardasil*[®] (three-dose schedule), on the National Immunisation Program (NIP).

The HPV vaccine is primarily delivered through school-based programs to adolescent females and males in years 7 or 8 (aged approximately 12 to 13 years) depending on your State or Territory as part of the NIP. You may see patients presenting in your clinic to receive missed school doses or seeking further information about HPV vaccination.

Key changes to the NIP-funded school-based human papillomavirus (HPV) vaccination program

- From January 2018, individuals aged approximately 12–13 years will be offered the 9-valent HPV vaccine (*Gardasil*[®]9) in a two-dose schedule through school-based programs.
- *Gardasil*[®]9 replaces the 4-valent HPV vaccine (*Gardasil*[®]), for which a three-dose schedule has been used.
- Two doses of *Gardasil*[®]9 spaced at least six months apart have been proven to have equivalent immunogenicity (and therefore clinical protection) in healthy individuals aged 9–14 years compared to a three-dose schedule in older individuals.
- *Gardasil*[®]9 includes the HPV types covered by *Gardasil*[®] (6, 11, 16 and 18) plus an additional five oncogenic HPV types (31, 33, 45, 52 and 58).
- A three-dose schedule is now only recommended for people who start (or have started) the vaccination course at age 15 years or older and for those of any age who have specific immunocompromising conditions.

The two doses of *Gardasil*[®]9 are recommended to be administered at an interval of between 6 to 12 months apart.

- If the second dose is inadvertently received at <6 months but ≥5 months after the first dose, a third dose is not required, as clinical trial data support this interval as still being sufficiently immunogenic.
- If the second dose is inadvertently received less than 5 months after the first dose, a third dose is required. The third dose should be given at least 3 months (12 weeks) after the second dose and at least 5 months after the first dose, whichever is later.
- While there is no upper time interval for administration of their second dose for those individuals who receive their first dose before turning 15 years, it is important to ensure timely completion of the schedule, and preferably before sexual debut, to maximise protection.

Immunocompromised individuals (with select major medical conditions) require three doses of *Gardasil*[®]9 to attain adequate protection.

- Those who should receive a three-dose schedule include individuals with the following major medical conditions: primary or secondary immunodeficiencies (B lymphocyte antibody and T lymphocyte complete or partial deficiencies); HIV infection; malignancy; organ transplantation; or significant immunosuppressive therapy (excluding asplenia or hyposplenia)¹.

- Such immunocompromised individuals aged 12–13 years are able to receive three doses of *Gardasil*[®]9 vaccine through the NIP. The vaccine should be administered at times 0 (first vaccination date), 2 and 6 months.
- Given the routine scheduling of school-based immunisation programs, immunocompromised individuals may be referred to their treating GP or primary care provider to ensure the completion of all three doses of *Gardasil*[®]9 vaccine. Individuals in which there is uncertainty of the need for two or three doses may also be referred.
- Three doses for immunocompromised individuals are funded through the NIP.

Individuals aged 15 years or older when receiving the first dose of *Gardasil*[®]9 require three doses of *Gardasil*[®]9 (as opposed to two). Please note: only two doses of *Gardasil*[®]9 are funded through the NIP catch up program for individuals aged up to 19 years.

- There is no evidence regarding the effectiveness of two doses of *Gardasil*[®]9 in individuals aged 15 years or over.
- Individuals should be encouraged to commence their *Gardasil*[®]9 schedule before age 15 years to maximise protection and schedule completion.
- If an individual receiving their first dose when 15 years or older purchases the third dose, a minimum interval of 6 months between the doses should be offered and planned for.

Individuals who have started a vaccine course with a different HPV vaccine (*Gardasil*[®] or *Cervarix*[®]) can have their course safely and effectively completed with *Gardasil*[®]9. See Table 1 for details.

- Individuals who commenced a *Gardasil*[®] schedule and complete it with *Gardasil*[®]9 will be adequately protected against the 4 HPV types covered by *Gardasil*[®].
- Re-vaccination with *Gardasil*[®]9 is NOT routinely recommended for individuals who have already completed a full schedule with either *Gardasil*[®] or *Cervarix*[®] vaccine.
- Individuals who have already received a completed schedule of *Gardasil*[®] through the NIP are not eligible for free *Gardasil*[®]9 vaccination.
- The most significant benefit from HPV vaccination is protection against the two most oncogenic types (HPV 16 and 18) which are responsible for a large proportion of HPV related cancers. All three HPV vaccines provide excellent protection against HPV 16 and 18.

1. The recommendation for a three-dose schedule does NOT apply to children aged ≤14 years with asplenia, asthma, chronic granulomatous disease, chronic heart/liver/lung/renal disease, CNS anatomic barrier defects (e.g., cochlear implant), complement deficiency, diabetes, or sickle cell disease, in the absence of any of the above conditions.

Recording of HPV vaccine doses given

HPV doses administered should be recorded in practice management software and reported to the National HPV Vaccination Program Register. Information on notifying HPV doses is available on the National HPV Vaccination Program Register website hpvregister.org.au/health-professionals/how-to-notify-hpv-doses

Table 1

Recommendations regarding doses of *Gardasil*[®]9 vaccine required for those who have already received one or more doses of another HPV vaccine (*Gardasil*[®] or *Cervarix*[®])

Number of HPV vaccine doses (any type) received previously at age ≤14 years **	Further <i>Gardasil</i> [®] 9 vaccine doses recommended [‡]
1 dose	One dose at least 6 months after the previous dose. Total of two doses will complete schedule.
2 doses with <6 months between doses	If the second dose is inadvertently received at <6 months but ≥5 months after the first dose, a third dose is not required. If the second dose is received less than 5 months after the first dose, a third dose is required, to be given at least 12 weeks after the second dose and at least 5 months after the first dose, whichever is later. Refer to your state or territory health department and/or the <i>Australian Immunisation Handbook 2018</i> if required.
2 doses with ≥6 months between doses	None. Two doses of any HPV vaccine greater than 6 months apart completes the schedule. Further doses of <i>Gardasil</i> [®] 9 are not recommended or funded.
≥3 doses	None [§] , if minimum intervals for a three-dose schedule are met [#] .
Number of HPV vaccine doses (any type) received with age at first dose ≥15 years**	Further <i>Gardasil</i> [®] 9 vaccine doses recommended
1 dose	Two doses. Second dose 2 months after previous dose (dose 1) and third dose 6 months after dose 1 [#] . A total of three doses completes the schedule. A third dose is not funded under the NIP.
2 doses with <6 months between doses	A third dose is <i>strongly recommended</i> to provide adequate protection [#] . A third dose is not funded under the NIP.
2 doses with ≥6 months between doses	A third dose is recommended to provide best protection [#] . A third dose is not funded under the NIP.
≥3 doses	None, if minimum intervals for a three dose schedule are met [#] .

* Individuals who are aged ≥15 years (i.e. on or passed their 15th birthday) at the time of their first HPV vaccine dose require a three-dose HPV vaccine schedule.

** Recommendations for two-dose schedule and minimum acceptable intervals for three-dose schedule are the same regardless of the type of HPV vaccine already received (i.e. all *Cervarix*[®], all *Gardasil*[®] or combination of both)

‡ For select immunocompromised individuals, a three-dose schedule (at 0, 2 and 6 months) is required for adequate protection against vaccine-type HPV.

All of the following recommended minimum intervals for a three-dose schedule have to be satisfied: at least 4 weeks between dose one and dose two; at least 12 weeks between dose two and dose three; and at least 5 months between dose one and dose three.



Refer to your state or territory health department and/or the Australian Immunisation Handbook 2018 update for further information.
health.gov.au/immunisation



Australian Government
Department of Health



National Immunisation Program

A joint Australian, State and Territory Government Initiative