



START THE DISCUSSION

GARDASIL[®]9 is a vaccine indicated for individuals 9 through 45 years of age for the prevention of infection caused by the human papillomavirus (HPV) types 6, 11, 16, 18, 31, 33, 45, 52 and 58 and the following diseases associated with the HPV types included in the vaccine: oropharyngeal and other head and neck cancers caused by HPV types 16, 18, 31, 33, 45, 52, and 58. GARDASIL[®]9 has been issued market authorization **with conditions**, pending the results of trials to verify its clinical benefit. Patients should be advised of the nature of the authorization.

For further information for GARDASIL[®]9 please refer to Health Canada's Notice of Compliance with conditions – drug products website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/notice-compliance/conditions.html>.

The effectiveness of GARDASIL[®]9 against oropharyngeal and other head and neck cancers caused by HPV types 16, 18, 31, 33, 45, 52 and 58 is based on the effectiveness of GARDASIL[®]* and GARDASIL[®]9 to prevent persistent infection and anogenital disease caused by HPV types covered by the vaccine.



NEW EXPANDED INDICATION: GARDASIL[®]9 is **now indicated with conditions** to help protect against certain **HPV-related oropharyngeal and other head and neck cancers** caused by HPV types **16, 18, 31, 33, 45, 52 and 58**.


GARDASIL[®]9

[Human Papillomavirus
9-valent Vaccine, Recombinant]

* GARDASIL[®] is no longer available/marketed in Canada.



GARDASIL[®]9 is the first and only vaccine indicated for the prevention of infection by 9 HPV types^{1*}

GARDASIL[®]9 (human papillomavirus 9-valent vaccine, recombinant) is also indicated in individuals 9 through 45 years of age for the prevention of infection caused by the human papillomavirus (HPV) types 6, 11, 16, 18, 31, 33, 45, 52 and 58 and the following diseases associated with the HPV types included in the vaccine: cervical, vulvar, vaginal, and anal cancer caused by HPV types 16, 18, 31, 33, 45, 52 and 58; genital warts (condyloma acuminata) caused by HPV types 6 and 11; and the following precancerous or dysplastic lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52 and 58: cervical adenocarcinoma *in situ* (AIS); cervical intraepithelial neoplasia (CIN) grade 2 and grade 3; cervical intraepithelial neoplasia (CIN) grade 1; vulvar intraepithelial neoplasia (VIN) grade 2 and grade 3; vaginal intraepithelial neoplasia (VaIN) grade 2 and grade 3; anal intraepithelial neoplasia (AIN) grades 1, 2, and 3.

* Comparative clinical significance is unknown.

THIS BOOKLET IS DESIGNED TO HELP YOU:

- 1. IDENTIFY ELIGIBLE PATIENTS**
- 2. START THE CONVERSATION**
- 3. PROVIDE ANSWERS TO COMMON QUESTIONS**



1. IDENTIFY ELIGIBLE PATIENTS

GARDASIL[®]9 is indicated in individuals aged 9–45 for the prevention of infection by **9 HPV types**.¹

If not immunized, most sexually active Canadians will have an asymptomatic HPV infection at some time²

HPV infections are **the most common STIs**²

- Most HPV infections occur **without symptoms** and resolve without treatment²
- They may lead to **cervical cancer** or other **HPV-related cancers and diseases**¹



Pro Tip #1:

Flag patient files as a reminder to recommend vaccination.



Persistent HPV infection can lead to several HPV-related cancers and diseases in men and women¹

Estimated incidence of HPV-related cancers and diseases in Canada during a one-year period (estimates for 2020)³⁻⁵

	MALE 	FEMALE 
Penile cancer ^{*†}	226	–
Anal cancer [*]	228	530
Vulvar and vaginal cancer [*]	–	1,114
Cervical cancer [*]	–	1,421
Oropharyngeal cancer [*]	1,015	232
Genital warts [‡]	29,272	23,663

Adapted from Bruni L. *et al.*, the 2021 Statistics Canada population estimates and Kliever E. *et al.*³⁻⁵

STI=sexually transmitted infection.

* Based on Canadian incidence rates in 2020.

† GARDASIL[®]9 is not indicated to prevent penile cancer.

‡ Based on an incidence in Manitoba in 2004 and generalized to Canada of 1.54/1,000 males and 1.23/1,000 females, and 2021 Canadian census data.

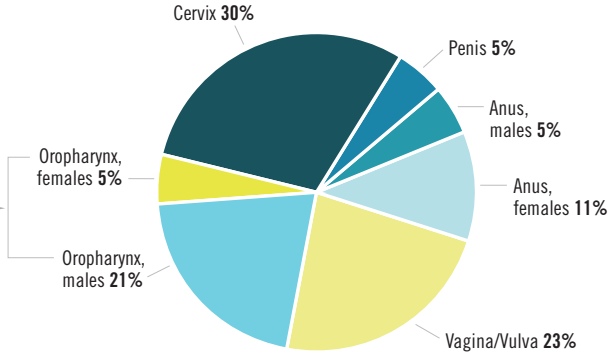


Why prevention matters

In 2020, 4,766 Canadians were diagnosed with an HPV-related cancer.³

Proportion of new cases for certain HPV-related cancers in 2020^{3*}

In 2020, the incidence rate of HPV-related oropharyngeal cancer was **4X higher in males** than females.³



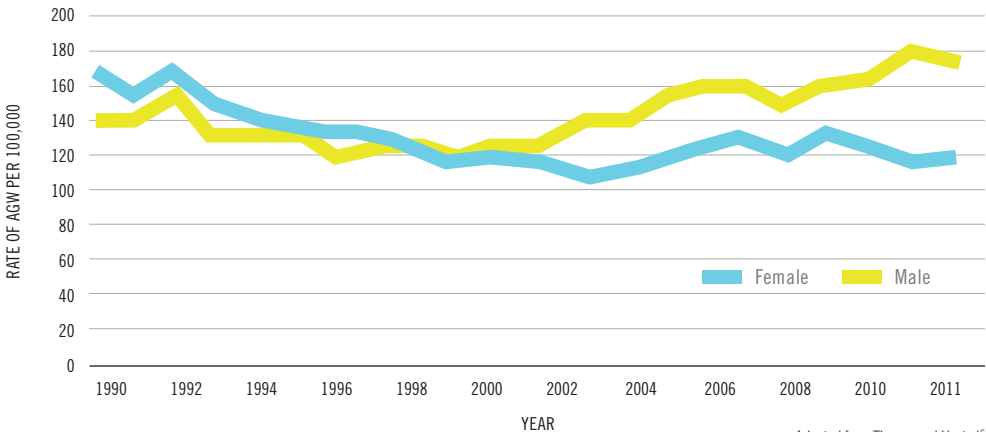
Adapted from Bruni L. *et al.*

GARDASIL[®]9 is now indicated with conditions to help protect against certain HPV-related oropharyngeal and other head and neck cancers.

HPV does not discriminate. Anyone who has ever been sexually active is at risk²

It is estimated that one Canadian develops genital warts **every 10 minutes**.^{4,5†}

Age-standardized incidence (per 100,000 persons) of AGW in Manitoba, 1990–2011^{6†}



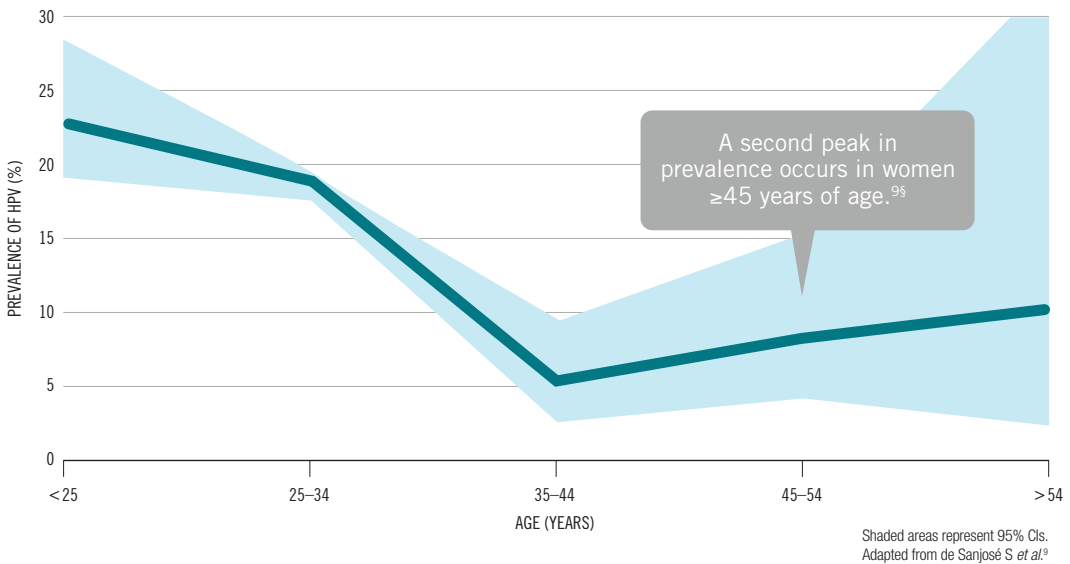
Adapted from Thompson LH *et al.*⁶

Efficacy in men 27 through 45 years of age for HPV types 6-, 11-, 16- and 18-related persistent infection, CIN (any grade), or external genital lesions (EGL) was inferred from efficacy data in women 24 through 45 years of age. For HPV types 6 and 11 in boys and men who were PCR-negative and seronegative at baseline, efficacy against penile/perineal/perianal intraepithelial neoplasia (PIN) grades 1/2/3 penile/perineal/perianal cancer was not demonstrated.

The risk of HPV infection can continue as long as a person is sexually active^{7§}

The peak risk for HPV infection in women is within the first 5–10 years of the first sexual experience.⁸

HPV prevalence by age among women with normal cytology in Northern America (Canada, USA and Greenland) between January 1995 to January 2005^{9§¶}



Pro Tip #2:
Display consumer materials in waiting room.

AGW=anogenital warts; CI=confidence intervals.

* Based on Canadian incidence rates in 2020.

† Based on an incidence in Manitoba in 2004 and generalized to Canada of 1.54/1,000 males and 1.23/1,000 females, and 2021 Canadian census data.^{4,5}

‡ Results from the 1990–2011 study to assess the incidence of AGW in males (n=16,302) and females (n=15,208) in Manitoba. Cases of AGW were identified using Manitoba's administrative databases of Physician Claims and Hospital Discharge Abstracts. Annual age-standardized incidence in Manitoba from 1990 to 2011 was calculated using Manitoba population data provided by the Health Information Management Branch of Manitoba Health, Healthy Living and Seniors each year.⁶

§ GARDASIL[®]9 is indicated for use in females 9 through 45 years of age.

¶ Meta-analysis based on a systematic literature review. 13 studies that included 25,813 patients were used to analyze data from Northern America (Canada, USA and Greenland).⁹

2. START THE CONVERSATION

Because your patients won't always bring it up with you!

- It is essential to initiate a discussion around HPV prevention and provide a **strong vaccination recommendation** to eligible patients*
- Reinforce the prevalence and impact of HPV

There are many opportunities to discuss HPV vaccination, for example:

- Routine checkups
- Recent change in relationship status
- During routine immunizations or travel vaccination discussions
- HPV screenings, such as routine Pap tests
- Contraception-related visits
- Sexual health/STI-related discussions
- Prior HPV infection or genital wart consults
- Colposcopies

YOU HAVE THE POWER to help prevent certain HPV-related cancers and diseases.¹

Conversation starters:

"I strongly recommend this vaccine to help protect you from cervical cancer, certain oropharyngeal and head and neck cancers, and other HPV-related cancers and diseases."¹

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"Have you had an HPV vaccine? Did you know approximately **75% of sexually active Canadians will have at least one HPV infection during their lifetime**? While most people clear the virus, those who don't can develop HPV-related cancers, such as oropharyngeal, cervical or anal cancers, or genital warts."^{1,10}

Reinforce the importance of vaccination

Estimated type contribution for certain HPV-related cancer and disease cases¹

	9 HPV types 6 11 16 18 31 33 45 52 58 cause a total of:
Cervical cancer cases [†]	90%
Cervical precancerous lesions [†]	75–85%
Low-grade cervical lesions [†]	50–60%
HPV-related vulvar cancer cases [†]	85–90%
HPV-related vaginal cancer cases [†]	80–85%
HPV-related anal cancer cases [†]	90–95%
HPV-related oropharyngeal cancers [†]	95%
Genital warts cases	90% (HPV types 6 & 11)

Adapted from the GARDASIL[®]9 Product Monograph.¹

Persistent infection with oncogenic HPV types is responsible for virtually all cases of invasive cervical cancer, approximately 70% of oropharyngeal cancers, 74% of vaginal cancers, approximately 25% of vulvar cancers and 80–90% of anal cancers. HPV types 6 and 11 cause 90% of genital warts (condyloma acuminata)¹.

CIN=cervical intraepithelial neoplasia.

* GARDASIL[®]9 is indicated for use in individuals 9 through 45 years of age.

† Not all cervical cancer/precancers, vulvar, vaginal, oropharyngeal and anal cancer cases are caused by HPV.

3. PROVIDE ANSWERS TO COMMON QUESTIONS

Q. Can I still get the HPV vaccine at my age?

A. GARDASIL[®]9 is indicated in individuals aged 9 to 45 to help protect against 9 HPV types that can lead to certain HPV-related cancers and diseases. The Protocole d'immunisation du Québec (PIQ) recommends HPV vaccination in that age group.^{1,11*†}

Q. Is it too late to get vaccinated if I'm already sexually active?

A. It may not be too late to help protect yourself against HPV.* And if you're already infected with one type of the virus, it might not be too late to help protect yourself against other types of HPV you haven't been exposed to.¹

Q. Will GARDASIL[®]9 still help me if I've already had HPV?

A. Even if you've already had an HPV infection, you can still receive HPV vaccination. If you're already infected with one type of HPV contained in the vaccine, GARDASIL[®]9 will help protect you against the other 8 types. The vaccine cannot treat an existing HPV infection, however.¹

Q. If I am a female and get vaccinated with GARDASIL[®]9, do I still need to get regular Pap tests?

A. A GARDASIL[®]9 vaccination will help protect you against 9 strains of HPV. Vaccination does not remove the need for screening for cervical, vulvar, vaginal, anal, oropharyngeal and other head and neck cancers. Routine Pap tests should remain part of your health schedule regardless of GARDASIL[®]9 administration, as they can help in the early detection of precancerous or cancerous cervical cells. Early detection and management of cervical dysplasia has been shown to have an impact on cervical cancer incidence and outcome. GARDASIL[®]9 is not indicated to manage and/or treat cervical cancer or dysplasia.^{1,10,12}

Q. Why should I get vaccinated if I only have one sexual partner?

A. GARDASIL®9 vaccination can help protect you in the event that you have a change in sexual partners one day. You can be at risk even if you have only one sexual partner because your partner may have had other partners in the past. HPV is a common virus. Without vaccination, the majority of sexually active people will catch HPV during their lifetime. Many people who have HPV may not show any signs or symptoms. This means that they can transmit (pass on) the virus to others without knowing it. Each partner in a sexual relationship may carry the infection for many years without knowing it because there are often no visible symptoms.^{1,7,10}

Q. Do I need to get all three doses of GARDASIL®9?

A. To complete the vaccination schedule, it is recommended to receive all 3 doses of GARDASIL®9. Alternatively, for those aged 9 through 14, GARDASIL®9 can be administered according to a 2-dose schedule.¹

- Dose 1: At a date you and your healthcare professional choose
- Dose 2: Between 5 and 13 months after first dose

If the second vaccine dose is given earlier than 5 months after the first dose, a third dose should always be given.¹

Q. Since our last discussion, I've had a change in relationship status, how can GARDASIL®9 help me?

A. A change in sexual behaviour or sexual partners is a risk factor for HPV.⁷

Q. Is GARDASIL®9 covered by insurance?

A. You may have private health insurance through work or school that covers vaccination with GARDASIL®9. Speak to your insurance company and visit our consumer website at gardasil9.ca to learn more.

GARDASIL®9 may not fully protect each person who gets it.

* GARDASIL®9 is indicated for use in individuals 9 through 45 years of age.¹
† Refer to the Protocole d'immunisation du Québec (PIQ) for complete recommendations.

Help protect your eligible patients with **GARDASIL®9**¹

Recommended schedule for GARDASIL®9¹

1. First dose: At elected date
2. Second dose: Administered 2 months after the first dose
3. Third dose: Administered 6 months after the first dose

The second dose should be administered at least 1 month after the first dose, and the third dose should be administered at least 3 months after the second dose. All 3 doses should be given within a 1-year period. Individuals are encouraged to adhere to the 0-, 2- and 6-month vaccination schedule.

In individuals 9 through 14 years of age, GARDASIL®9 can be administered according to a 2-dose schedule¹

1. First dose: At elected date
2. Second dose: Administered between 5 and 13 months after the first dose

If the second vaccine dose is administered earlier than 5 months after the first dose, a third dose should always be administered.

Please refer to the Product Monograph for complete dosing information.

Contraindications:

- Patients who are hypersensitive to either GARDASIL®* or GARDASIL®9 or to any ingredient in the formulation or component of the container
- Individuals who develop symptoms indicative of hypersensitivity after receiving a dose of GARDASIL®9 or GARDASIL®* should not receive further doses of GARDASIL®9

Relevant warnings and precautions:

- May not result in protection in all vaccine recipients
- Not intended to be used for treatment of active external genital lesions; cervical, vulvar, vaginal, anal, oropharyngeal, and other head and neck cancers; CIN, VIN, VaIN or AIN
- Will not protect against diseases that are not caused by HPV
- Not been shown to protect against diseases due to all HPV types
- Appropriate medical treatment should always be readily available in case of rare anaphylactic reactions following administration of the vaccine
- Syncope (fainting) may follow any vaccination, especially in adolescents and young adults. Syncope, sometimes associated with falling, has occurred after vaccination. Therefore, vaccinees should be carefully observed for approximately 15 minutes after administration of GARDASIL®9
- Routine monitoring and Pap test in women should continue to be performed as indicated
- Do not discontinue screening for cervical, vulvar, vaginal, anal, oropharyngeal and other head and neck cancers if it has been recommended by a healthcare provider
- Consider delaying vaccination in presence of febrile illness
- Immunocompromised, including HIV, patients may have a reduced antibody response
- Safety and efficacy have not been evaluated in geriatric (≥65 years of age) and pediatric (<9 years of age) patients
- Give with caution to patients with bleeding disorders
- Use appropriate precautions against sexually transmitted diseases
- Pregnancy should be avoided during the vaccination regimen
- Not known whether vaccine antigens are excreted in human milk

For more information:

Please consult the **GARDASIL®9 Product Monograph** at https://www.merck.ca/static/pdf/GARDASIL_9-PM_E.pdf for important information relating to adverse reactions, drug interactions and dosing information which have not been discussed in this piece.

The Product Monograph is also available by calling 1-800-567-2594.

* GARDASIL® is no longer available/marketed in Canada.

References: 1. Merck Canada Inc. GARDASIL®9 Product Monograph. April 6, 2022. 2. Public Health Agency of Canada. Human papillomavirus vaccine: Canadian Immunization Guide. Available at: <https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-9-human-papillomavirus-vaccine.html>. Last accessed May 23, 2022. 3. Bruni L *et al.* ICO/IARC Information Centre on HPV and Cancer (HPV Information Centre), Human Papillomavirus and Related Diseases in Canada. Summary Report 22 October 2021. Available at: <https://hpvcentre.net/statistics/reports/CAN.pdf?i=1565188933974>. Last accessed May 23, 2022. 4. Statistics Canada. Population estimates on July 1st, 2021, by age and sex. Available at: <https://www150.statcan.gc.ca/t1/tbl1/en/tv.action?pid=1710000501>. Last accessed May 23, 2022. 5. Kliever E *et al.* Twenty-year trends (1985-2004) in the incidence and prevalence of anogenital warts in Manitoba. *Cancer Care Manitoba*, 2008. 6. Thompson LH *et al.* Increasing incidence of anogenital warts with an urban-rural divide among males in Manitoba, Canada, 1990-2011. *BMC Public Health* 2016;16:219. 7. Public Health Agency of Canada. Canadian Guidelines on Sexually Transmitted Infections: Human Papillomavirus (HPV) Infections Chapter. Available at: <http://www.phac-aspc.gc.ca/std-mts/sti-tis/cgsti-ldcits/assets/pdf/section-5-5a-eng.pdf>. Last accessed May 23, 2022. 8. Public Health Agency of Canada. An Advisory Committee Statement (ACS) National Advisory Committee on Immunization (NACI). Update on Human Papillomavirus (HPV) Vaccines. *CCDR* 2012;38:ACS-1. 9. de Sanjosé S *et al.* Worldwide prevalence and genotype distribution of cervical human papillomavirus DNA in women with normal cytology: a meta-analysis. *Lancet Infect Dis* 2007;7(7):453-9. 10. The Society of Obstetricians and Gynaecologists of Canada. What is HPV? Available at: www.hpvinfo.ca. Last accessed May 23, 2022. 11. Protocole d'immunisation du Québec (PIO). Vaccins. VPH : vaccin contre les virus du papillome humain. March 10, 2021. Available at: <https://mss.gouv.qc.ca/professionnels/vaccination/piq-vaccins/vph-vaccin-contre-les-virus-du-papillome-humain/>. Last accessed May 23, 2022. 12. Canadian Cancer Statistics 2016. Special topic: HPV-associated cancers. Available at: <http://www.cancer.ca/~media/cancer.ca/CW/cancer%20information/cancer%20101/Canadian%20cancer%20statistics/Canadian-Cancer-Statistics-2016-EN.pdf?i=en>. Last accessed October 21, 2021.