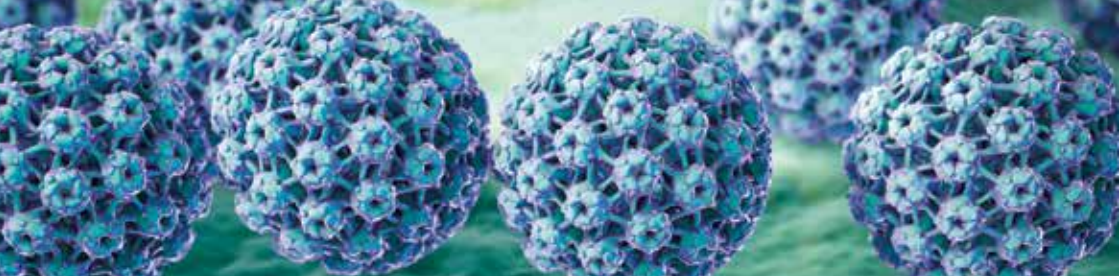

החיסון נגד וירוס הפפילומה

למי?	מתי?	איפה?
 נשים וגברים 18-26	 שלוש מנות 0,2,6 חודשים[1]	ניתן לרכוש בהנחה דרך הביטוחים המשלימים של קופות החולים ובביקור רופא. זמין גם בבתי המרקחת הפרטיים
 ילדים וילדות 9-14	 שתי מנות 0,6 חודשים[1]	זכאים לקבל את החיסון בבתי הספר (תלמידי כיתה ח')[2] ובלשכות הבריאות[3]
 נערים ונערות 15-18	 שלוש מנות 0,2,6 חודשים[1]	זכאים לקבל את החיסון בחינם*, לקביעת תור יש להתקשר ל"קול הבריאות" *5400[3]

גרדסיל 9 מתווה לגילאי 9-26[1] למידע נוסף לגבי בני 27-45, יש לעיין בתדריך החיסונים[2]

* הזכאות היא עבור חיסון כנגד וירוס הפפילומה האנושי וניתנת לבנות ילידות שנת 1999 ומעלה ובנים ילידי שנת 2001 ומעלה שלא חוסנו במסגרת כיתה ח'.

1. Gardasil® 9, Prescribing Information, February 2017
2. משרד הבריאות, האגף לאפידמיולוגיה, תדריך חיסונים, עדכון מרץ 2019 חיסונים נגד זיהומים הנגרמים על ידי נגיף הפפילומה באדם https://www.health.gov.il/UnitsOffice/HD/PH/epidemiology/td/docs/350_HPV.pdf (Accessed in 19/5/2019)
3. משרד הבריאות, חיסון נגד נגיף הפפילומה https://www.health.gov.il/Subjects/vaccines/HPV/Pages/default.aspx

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GARDASIL 9
Human Papillomavirus 9-valent Vaccine
(Recombinant, adsorbed)

GARDASIL®9

Human Papillomavirus 9-valent Vaccine (Recombinant, adsorbed)

Gardasil 9 Selected Safety Information

INDICATION:

GARDASIL® 9 is indicated for active immunisation of individuals at the age of 9-26 years old against the following HPV diseases: Premalignant lesions and cancers affecting the cervix, vulva, vagina and anus caused by vaccine HPV types, Genital warts (Condyloma acuminata) caused by specific HPV types.

CONTRAINDICATIONS:

Hypersensitivity to the active substances or to any of the excipients.

Individuals with hypersensitivity after previous administration of GARDASIL® 9 or GARDASIL® should not receive GARDASIL® 9.

PRECAUTIONS/WARNINGS:

The decision to vaccinate an individual should take into account the risk for previous HPV exposure and potential benefit from vaccination.

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of rare anaphylactic reactions following the administration of the vaccine. Syncope (fainting), sometimes associated with falling, can occur following, or even before, any vaccination, especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia, and tonic-clonic limb movements during recovery. Therefore, vaccinees should be observed for approximately 15 minutes after vaccination. It is important that procedures are in place to avoid injury from fainting. Vaccination should be postponed in individuals suffering from an acute severe febrile illness. However, the presence of a minor infection, such as a mild upper respiratory tract infection or low-grade fever, is not a contraindication for immunisation. As with any vaccine, vaccination with GARDASIL® 9 may not result in protection in all vaccine recipients. The vaccine will only protect against diseases that are caused by HPV types targeted by the vaccine. Therefore, appropriate precautions against sexually transmitted diseases should continue to be used. The vaccine is for prophylactic use only and has no effect on active HPV infections or established clinical disease. The vaccine has not been shown to have a therapeutic effect. The vaccine is therefore not indicated for treatment of cervical, vulvar, vaginal and anal cancer, high-grade cervical, vulvar, vaginal and anal dysplastic lesions or genital warts. It is also not intended to prevent progression of other established HPV-related lesions. GARDASIL® 9 does not prevent lesions due to a vaccine HPV type in individuals infected with that HPV type at the time of vaccination. Vaccination is not a substitute for routine cervical screening. Since no vaccine is 100% effective and GARDASIL® 9 will not provide protection against every HPV type, or against HPV infections present at the time of vaccination, routine cervical screening remains critically important and should follow local recommendations. There are no data on the use of GARDASIL® 9 in individuals with impaired immune responsiveness. Safety and immunogenicity of a qHPV vaccine have been assessed in individuals aged from 7 to 12 years who are known to be infected with human immunodeficiency virus (HIV).

Individuals with impaired immune responsiveness, due to either the use of potent immunosuppressive therapy, a genetic defect, Human Immunodeficiency Virus (HIV) infection, or other causes, may not respond to the vaccine. This vaccine should be given with caution to individuals with thrombocytopaenia or any coagulation disorder because bleeding may occur following an intramuscular administration in these individuals. There are no safety, immunogenicity or efficacy data to support interchangeability of GARDASIL® 9 with bivalent or quadrivalent HPV vaccines.

ADVERSE REACTIONS:

A total of 15,776 individuals (10,495 subjects 16 through 26 years of age and 5,281 adolescents 9 through 15 years of age at enrolment) received GARDASIL® 9 in clinical trials. Few individuals (0.1%) discontinued due to adverse experiences. The most common adverse reactions observed with GARDASIL® 9 were injection-site adverse reactions (84.8% of vaccinees within 5 days following any vaccination visit) and headache (13.2% of the vaccinees within 15 days following any vaccination visit). These adverse reactions usually were mild or moderate in intensity. The common adverse events were dizziness, nausea, pyrexia, fatigue, and pruritus and bruising at the injection site.

CLINICALLY SIGNIFICANT INTERACTIONS:

Safety and immunogenicity in individuals who have received immunoglobulin or blood-derived products during the 3 months prior to vaccination have not been studied in clinical trials. **Use with other vaccines:** GARDASIL® 9 may be administered concomitantly with a combined booster vaccine containing diphtheria (d) and tetanus (T) with either pertussis [acellular, component] (ap) and/or poliomyelitis [inactivated] (IPV) (dTap, dT-IPV, dTap-IPV vaccines) with no significant interference with antibody response to any of the components of either vaccine. This is based on the results from a clinical trial in which a combined dTap-IPV vaccine was administered concomitantly with the first dose of GARDASIL® 9. **Use with hormonal contraceptives:** In clinical studies, 60.2% of women aged 16 through 26 years who received GARDASIL® 9 used hormonal contraceptives during the vaccination period of the clinical studies. Use of hormonal contraceptives did not appear to affect the type specific immune responses to GARDASIL® 9.

CLINICALLY SIGNIFICANT USE IN SPECIFIC POPULATIONS:

Pregnancy - A large amount of data on pregnant women (more than 1000 pregnancy outcomes) indicates no malformative nor foeto/neonatal toxicity of GARDASIL® 9. Animal studies do not indicate reproductive toxicity. However, these data are considered insufficient to recommend use of GARDASIL® 9 during pregnancy. Vaccination should be postponed until completion of pregnancy. **Breast-feeding** - GARDASIL® 9 can be used during breast-feeding.

DOSING:

Individuals 9 to and including 14 years of age at time of first injection - GARDASIL® 9 can be administered according to a 2 dose schedule (see section 5.1). The second dose should be 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. GARDASIL® 9 can be administered according to a 3-dose (0, 2, 6 months) schedule. The second dose should be administered at least one month after the first dose and the third dose should be administered at least 3 months after the second dose. All three doses should be given within a 1-year period. I**ndividuals 15-26 years of age at time of first injection** - GARDASIL® 9 should be administered according to a 3-dose (0, 2, 6 months) schedule. The second dose should be administered at least one month after the first dose and the third dose should be administered at least 3 months after the second dose. All three doses should be given within a 1-year period. The use of GARDASIL® 9 should be in accordance with official recommendations. It is recommended that individuals who receive a first dose of GARDASIL® 9 complete the vaccination course with GARDASIL® 9. The need for a booster dose has not been established. Studies using a mixed regimen (interchangeability) of HPV vaccines were not performed for GARDASIL® 9. Subjects previously vaccinated with a 3-dose regimen of quadrivalent HPV types 6, 11, 16, and 18 vaccine (GARDASIL®), hereafter referred to as qHPV vaccine, may receive 3 doses of GARDASIL® 9.

לפני מתן מרשם יש לעיין בעלון לרופא כפי שאושר ע"י משרד הבריאות

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