

הנדון: Gardasil® 9
גרדסיל 9**Dosage Form:** Suspension for injection**Composition:**

HPV TYPE 58 L1 PROTEIN 20 MCG / 0.5 ML
HPV TYPE 52 L1 PROTEIN 20 MCG / 0.5 ML
HPV TYPE 45 L1 PROTEIN 20 MCG / 0.5 ML
HPV TYPE 33 L1 PROTEIN 20 MCG / 0.5 ML
HPV TYPE 31 L1 PROTEIN 20 MCG / 0.5 ML
HPV TYPE 18 L1 PROTEIN 40 MCG / 0.5 ML
HPV TYPE 16 L1 PROTEIN 60 MCG / 0.5 ML
HPV TYPE 11 L1 PROTEIN 40 MCG / 0.5 ML
HPV TYPE 6 L1 PROTEIN 30 MCG / 0.5 ML

חברת מרק שארפ ודוהם (ישראל-1996) בע"מ (MSD ישראל), מבקשת ליידע על עדכון העלון לרופא של גרדסיל 9.

עדכונים מהותיים שבוצעו בעלון לרופא (טקסט שהוסף לעלון לרופא מודגש בקו תחתון, טקסט שנמחק מהעלון לרופא מסומן בקו חוצה):

4.8 Undesirable effects

...
qHPV vaccine

Table 2 includes adverse experiences that have been spontaneously reported during post-approval use of qHPV vaccine ~~and may also be seen in post-marketing experience with Gardasil 9~~. The post-marketing safety experience with qHPV vaccine is relevant to Gardasil 9 since the vaccines contain L1HPV proteins of 4 of the same HPV types.

5.1 Pharmacodynamic properties

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Pregnancy

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During the clinical development of Gardasil 9; 2,586 women (1,347 in the Gardasil 9 group vs. 1,239 in the qHPV vaccine group) reported at least one pregnancy. The types of anomalies or proportion of pregnancies with an adverse outcome in individuals who received Gardasil 9 or qHPV vaccine were comparable and consistent with the general population ([see section 4.6](#)).

Prevention of juvenile-onset recurrent respiratory papillomatosis (JoRRP) by vaccination of girls and women of childbearing potential

JoRRP is caused by upper airway infection primarily with HPV types 6 and 11, acquired vertically (mother-to-child) during childbirth. Observational studies in the US and Australia have shown that the introduction of qHPV vaccine since 2006 has led to declines in the incidence of JoRRP at population level.

6.4 Special precautions for storage

Gardasil 9 suspension for injection:

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Stability data indicate that the vaccine components are stable for 7296 hours when stored at temperatures from 8°C to 2540°C or for 72 hours when stored at temperatures from 0°C to 2°C. At the end of this period Gardasil 9 should be used or discarded. These data are intended to guide healthcare professionals in case of temporary temperature excursion only.

Gardasil 9 suspension for injection in a pre-filled syringe:

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בעלון לרופא נמחק היצרן ועודכן כתובת בעל הרישום והיבואן בהתאם לרישיון.

בעלון לרופא לא היו עדכונים נוספים.

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס על ידי פניה לבעל הרישום, חברת MSD, בטלפון 09-9533333. **Gardasil 9** מופצת ע"י חברת נובולוג בע"מ.

בברכה,
מיכל סרפר, רוקחת ממונה
MSD ישראל

References:

Israeli approved SPC revised on 5/2023