



אוג' 2026

ADACEL POLIO

חומר פעיל:

Diphtheria Toxoid	2 LF / 1 DOSES
Tetanus Toxoid	5 LF / 1 DOSES
Fimbriae Types 2 + 3 (FIM)	5 MCG/DOSE
Pertussis Toxoid Vaccine	2.5 MCG/DOSE
Filamentous Haemagglutinin (FHA)	5 MCG/DOSE
Pertactin (PRN)	3 MCG/DOSE
Inactivated Polio Virus (IPV) Type 1	40 DU/DOSE
Inactivated Polio Virus (IPV) Type 2	8 DU/DOSE
Inactivated Polio Virus (IPV) Type 3	32 DU/DOSE

ההתוויה המאושרת:

Active immunization against diphtheria, tetanus, pertussis and poliomyelitis in subjects aged 4 years and over as a booster following primary immunisation. Adacel polio is not indicated for primary immunisation. Adacel polio is not indicated for treating diseases caused by B.pertussis, C.Diphtheriae or C.tetani or by poliomyelitis infections.

חברת סאנופי ישראל מבקשת להודיע על עדכון העלון לצרכן במתכונת עלון לרופא.

העדכונים העיקריים הינם (מידע שהתווסף מסומן בקו תחת, מידע שהוסר מסומן בקו חוצה, החמרות מסומנות בצהוב, עדכוני עלון מסוג אחר מסומנים ב- track changes באדום):

1. NAME OF THE MEDICINAL PRODUCT

ADACEL-POLIO, suspension for injection, in pre-filled syringe

Diphtheria, Tetanus, Pertussis (acellular, component) and Poliomyelitis (inactivated) Vaccine (adsorbed, reduced antigen(s) content)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 dose (0.5 mL) contains:

Diphtheria toxoid	Not less than 2 IU* (2 Lf)
Tetanus toxoid	Not less than 20 IU* (5 Lf)
Pertussis antigens	



Pertussis toxoid (PT)	2.5 micrograms
Filamentous haemagglutinin (FHA)	5 micrograms
Fimbriae types 2 + 3 (FIM)	5 micrograms
Pertactin (PRN)	3 micrograms
Poliovirus (Inactivated)**	
Type 1 (Mahoney)	40 D antigen units
Type 2 (MEF1)	8 D antigen units
Type 3 (Saukett)	32 D antigen units
Adsorbed on aluminum phosphate	1.5 mg (0.33 mg Al ³⁺)

* As lower confidence limit ($p = 0.95$) of activity measured according to the assay described in the European Pharmacopoeia.

** Cultivated on Vero cells.

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4.5 Interaction with other medicinal products and other forms of interaction

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Based on the results of concomitant use clinical studies, ADACEL-POLIO can be administered with human papilloma virus vaccine (HPV) and/or Meningococcal Polysaccharide (Serogroups A, C, Y, and W) (MenACYW) conjugate vaccines (either all three vaccines concomitantly or in pairs) (see section 4.8) according to local recommendations.

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4.8 Undesirable effects

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The safety analysis of concomitant use of either ADACEL POLIO or ADACEL administered with MenACYW (Menactra or MenQuadfi) and/or HPV (Gardasil or Gardasil 9) vaccines included 5 122 healthy male and female subjects aged 10 to 17 years from 6 clinical trials.

The overall safety profile of ADACEL POLIO or ADACEL was similar when all three vaccines were administered concomitantly compared to coadministered pairs (ADACEL and Menactra or ADACEL POLIO /ADACEL and Gardasil/Gardasil 9). The safety profile of coadministered ADACEL POLIO and Gardasil/Gardasil 9 was similar to Gardasil/Gardasil 9 administered alone.



In clinical studies, injection-site reactions (pain, erythema, swelling, and bruising), as well as headache, malaise, and myalgia were observed more frequently when all three vaccines were administered together or in pairs, compared to when they were administered alone. Overall, the differences observed in injection site reactions were < 10%, while the differences in headache, malaise, and myalgia ranged from < 10% to < 28%. The difference in fever rates across clinical studies was < 2%.

The majority of adverse events were reported as mild to moderate in intensity.

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6.1 List of excipients

2-Phenoxyethanol, Ethanol, Aluminum phosphate, Polysorbate 80, Water for injection.

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לתשומת ליבכם, לא חל שינוי בהרכב התכשיר.

העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס על ידי פנייה לבעל הרישום - סאנופי ישראל בע"מ, Greenwork Park, מתחם העסקים בקיבוץ יקום, בניין E (קומה 1), 6097600, יקום או בטלפון: 09-8633081.

להלן הקישור לאתר משרד הבריאות: <https://israel drugs.health.gov.il/#!/byDrug>

בברכה,

חברת סאנופי ישראל בע"מ