יול' 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 Haemogglutinin (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 תחתי, 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 ~~(reduced antigen content)~~, 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 ~~adsorbed~~ Not less than 2 IU* (2 Lf)

Tetanus toxoid ~~adsorbed~~ Not less than 20 IU* (5 Lf)

Pertussis antigens ~~adsorbed:~~

Pertussis toxoid (PT)~~adsorbed~~ 2.5 micrograms

Filamentous haemagglutinin (FHA)~~adsorbed~~ 5 micrograms

Fimbriae types 2 + 3 (FIM)~~adsorbed~~ 5 micrograms

Pertactin (PRN) ~~adsorbed~~ 3 micrograms

Poliovirus (Inactivated)**

~~Poliomyelitis virus type~~ Type 1 (Mahoney)~~** (inactivated)~~ ~~40~~ D antigen units

~~Poliomyelitis virus type~~ Type 2 (MEF1)~~* * (inactivated)~~ ~~8~~ D antigen units

~~Poliomyelitis virus type~~ Type 3 (Saukett)~~** (inactivated)~~ 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.

~~*~~** ~~Produced~~ Cultivated o~~i~~n 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 ~~may~~ can be administered ~~concurrently~~ with ~~a dose of recombinant Human Papillomavirus~~human papilloma virus vaccine (HPV) and/or Meningococcal Polysaccharide (Serogroups A, C, Y, and W) (MenACYW) conjugate vaccines ~~(with no significant interference with antibody response to any of the components of~~ either ~~vaccine. However, a trend of lower anti-HPV GMTs was observed in the concomitant group. The clinical significance of this observation is not known. This is based on the results from a clinical trial in which ADACEL-POLIO was administered~~all three vaccines concomitantly ~~with the first dose of Gardasil~~or in pairs) (see section 4.8) according to 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 ~~In a~~ clinical ~~trial of 843 healthy adolescent males and females 11-17 years of age, administration~~trials.

The overall safety profile of ADACEL POLIO or ADACEL was similar when all three vaccines were administered~~the first dose of Gardasil~~ 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.~~with ADACEL POLIO showed that there was more~~

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, there~~reported following concomitant administration. The~~ differences observed in injection site reactions were < 10%, while~~% and in~~ 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 ~~subjects, the~~ adverse events were reported as mild to moderate in intensity.

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6.1 List of excipients

2-Phenoxyethanol, Ethanol, Aluminum phosphate, ~~Ethanol,~~ 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://israeldrugs.health.gov.il/#!/byDrug

בברכה,

חברת סאנופי ישראל בע"מ