יולי 2024

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.
העלון לצרכן במתכונת עלון לרופא ובו מסומנים העדכונים העיקריים, מצורף למכתב זה.

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

1. NAME OF THE MEDICINAL PRODUCT

ADACEL®-POLIO, suspension for injection, in ~~a~~ pre-filled syringe

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 dose (0.5 mL) contains:

Diphtheria toxoid adsorbed ~~Not less than IU*~~	Not less than 2 IU* (2 Lf)
Tetanus toxoid adsorbed	Not less than 20 IU* (5 Lf)
Pertussis antigens adsorbed:	
Pertussis toxoid adsorbed	2.5 micrograms
Filamentous haemagglutinin adsorbed	5 micrograms
Fimbriae types 2 + 3 adsorbed	5 micrograms
Pertactin adsorbed	3 micrograms
Poliomyelitis virus type 1 (Mahoney)** (inactivated)	40 D antigen units
Poliomyelitis virus type 2 (MEF1)** (inactivated)	8 D antigen units
Poliomyelitis virus type 3 (Saukett)** (inactivated)	32 D antigen units
Adsorbed on aluminum phosphate	1.5 mg (0.33 mg Al^{3+})

~~* or the equivalent antigen quantity, determined by suitable immunochemical method~~

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

** Produced in Vero cells.

ADACEL POLIO may contain traces of formaldehyde, glutaraldehyde, streptomycin, neomycin, polymyxin B and bovine serum albumin, which are used during the manufacturing process (see sections 4.3 and 4.4).

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Suspension for injection in a pre-filled syringe.

ADACEL®-POLIO appears as a uniform, cloudy, white~~ish~~ suspension.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

[…]

4.2 Posology and method of administration

[…]

4.3 Contraindications

[…]

4.4 Special warnings and precautions for use

[…]

Other considerations
As with any vaccine, a protective immune response may not be elicited in all vaccines (see section 5.1).
Limited data indicate that maternal antibodies may reduce the magnitude of the immune response to some vaccines in infants born to women vaccinated with ADACEL®-POLIO during pregnancy.
A persistent nodule at the site of injection may occur with all adsorbed vaccines, particularly if administered into the superficial layers of the subcutaneous tissue.
Traceability

In order to improve the traceability of biological medicinal products, the name of the administered product should be clearly recorded. It is recommended to record the batch number as well.

Excipients with known effects

ADACEL-POLIO contains 1.01 milligram of alcohol (ethanol) in each 0.5 mL dose. The small amount of alcohol in this medicine will not have any noticeable effects.

4.5 Interaction with other medicinal products and other forms of interaction

[…]

4.6 Fertility, pregnancy and lactation

[…]

4.7 Effects on ability to drive and use machines

[…]

4.8 Undesirable effects

[…]

4.9 Overdose

Not applicable.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Bacterial and viral vaccines combined. Vaccine against diphtheria, tetanus, pertussis and poliomyelitis
ATC Code: J07CA02

Clinical trials

[…]

5.2 Pharmacokinetic properties

[…]

5.3 Preclinical safety data

[…]

6. Pharmaceutical particulars
6.1 List of excipients

Phenoxyethanol, Aluminum phosphate, Ethanol, Polysorbate 80, Water for injection.~~s~~

For adjuvant see section 2.

Manufacturing Process Residuals:

The final product may contain trace amount of formaldehyde, glutaraldehyde, streptomycin, neomycin, polymyxin B, bovine serum albumin (trace).

6.2 Incompatibilities

[…]

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage

[…]

6.5 Nature and contents of container

0.5 mL of suspension in pre-filled syringe (glass) with a plunger stopper (~~chlorobromobutyl or bromobutyl or~~ chlorobutyl elastomer), without attached needle, with a tip-cap (~~chlorobromobutyl elastomer or~~ synthetic isoprene-bromobutyl elastomer) - pack size of 1, 10 or 20.
0.5 mL of suspension in pre-filled syringe (glass) with a plunger stopper (~~chlorobromobutyl or bromobutyl or~~ chlorobutyl elastomer), without attached needle, with a tip-cap (~~chlorobromobutyl elastomer or~~ synthetic isoprene-bromobutyl elastomer) and 1 or 2 separate needles - pack size of 1 or 10.
~~0.5 mL of suspension in pre-filled syringe (glass) with a plunger stopper (chlorobromobutyl or bromobutyl or chlorobutyl elastomer) with attached needle and needle guard (translucent polypropylene rigid safeshield and polyisoprene) - pack size of 1, 10 or 20.~~
~~The stoppers, plunger stoppers and caps for all presentations of ADACEL® POLIO are latex-free.~~
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

[…]

7. ~~LICENSE~~ MARKETING AUTHORISATION HOLDER:

Sanofi Israel Ltd., Greenwork Park, P.O box 47, Yakum ~~Medici Medical Ltd., 3 Hamachshev St. Netanya~~

~~8. MANUFACTURER:~~

~~Sanofi Pasteur, 14 Espace Henry Vallee, 69007 LYON- FRANCE~~

~~9~~8. MARKETING AUTHORISATION NUMBER

142-60-31938-00

~~Approved in: February 2015~~

Revised in: June~~August~~ 202~~4~~0.