



דצמבר 2024

PENTAXIM

חומרים פעילים:

DIPHTHERIA TOXOID (Not less than) – 30 IU / 0.5 ml
TETANUS TOXOID (Not less than) – 40 IU / 0.5 ml
PERTUSSIS TOXOID (PT) – 25 MCG / 0.5 ML
FILAMENTOUS HAEMAGGLUTININ (FHA) – 25 MCG / 0.5 ML
POLIOVIRUS TYPE 1 (MOHONEY) – 40 DU / 0.5 ML
POLIOVIRUS TYPE 2 (M.E.F.1) – 8 DU / 0.5 ML
POLIOVIRUS TYPE 3 (SAUKETT) – 32 DU / 0.5 ML
HAEMOPHILUS INFLUENZAE TYPE B POLYSACCHARIDE –10 MCG / 0.5 ML
CONJUGATED TO TETANUS PROTEIN – 18 - 30 MCG / 0.5 ML

התוויות מאושרות:

Active immunisation against diphtheria, tetanus, pertussis, poliomyelitis and invasive infections caused by Haemophilus influenzae type b (meningitis, septicaemia, cellulitis, arthritis, epiglottitis, ...)

- for primary vaccination in infants.
- for booster in children who have previously received a primary vaccination with this vaccine or a diphtheria-tetanus-whole-cell or acellular pertussis poliomyelitis vaccine, whether mixed or not with freeze-dried conjugate Haemophilus influenzae type b vaccine.

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://israel drugs.health.gov.il/#!/byDrug>

בברכה,

חברת סאנופי ישראל בע"מ

1. NAME OF THE MEDICINAL PRODUCT

PENTAXIM

Diphtheria, tetanus, pertussis (acellular, component), poliomyelitis (inactivated) and Haemophilus influenzae type b conjugate vaccine (adsorbed)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

~~Each~~ One dose (0.5 ml) ~~dose~~ of reconstituted vaccine contains:

Purified diphtheria toxoid ¹	not less than 30 I-U ^{2,3}
Purified tetanus toxoid ¹	not less than 40 I-U ^{3,4}
Purified pertussis toxoid (PTxd) ¹	25 µg
Purified filamentous haemagglutinin (FHA) ¹	25 µg
Inactivated type 1 (<u>Mahoney</u>) poliovirus ⁵	D antigen ⁶ : 40 units
Inactivated type 2 (<u>MEF-1</u>) poliovirus ⁵	D antigen ⁶ : 8 units
Inactivated type 3 (<u>Saukett</u>) poliovirus ⁵	D antigen ⁶ : 32 units
Haemophilus influenzae type b polysaccharide..... conjugated to tetanus protein	10 µg

¹ Adsorbed on aluminium hydroxide, hydrated (0.3 mg Al³⁺)

² As lower confidence limit (p= 0.95) and not less than 30 IU As-as
mean value ___

³ Or equivalent activity determined by immunogenicity evaluation

⁴ As lower confidence limit (p = 0.95)

⁵ Produced on Vero cells

⁶ Or equivalent antigenic quantity determined by a suitable immunochemical method

Pentaxim ~~solution-suspension~~ for injection is obtained by reconstitution of the powder of conjugate Haemophilus influenzae type b vaccine (vial) with the suspension of combined diphtheria, tetanus, acellular pertussis and inactivated poliomyelitis vaccine, adsorbed (pre-filled syringe).

The vaccine may contain traces of glutaraldehyde, neomycin, streptomycin and polymyxin B (see section 4.4).

Excipients with known effect

Phenylalanine.....12.5 micrograms

(See section 4.4)

For the full list of excipients, see section 6.1.