



אוגוסט 2024

## Vaxigrip Tetra

חומר פעיל:

Influenza virus (inactivated, split) of the following strains\*:

A/Victoria/4897/2022 (H1N1)pdm09-like strain (A/Victoria/4897/2022, IVR-238) – 15 micrograms HA\*\*

A/Darwin/9/2021 (H3N2) - like strain (A/Darwin/9/2021, IVR-228) – 15 micrograms HA\*\*

B/Austria/1359417/2021 - like strain (B/Michigan/01/2021, wild type) – 15 micrograms HA\*\*

B/Phuket/3073/2013 - like strain (B/Phuket/3073/2013, wild type) – 15 micrograms HA\*\*

Per 0.5 ml dose

\*propagated in fertilised hens' eggs from healthy chicken flocks

\*\*haemagglutinin

ההתוויה המאושרת:

Vaxigrip Tetra (Quadrivalent Influenza Vaccine (split virion, inactivated) is indicated for the prevention of influenza disease caused by the two influenza A virus subtypes and the two influenza B virus types contained in the vaccine for:

-active immunisation of adults, including pregnant women, and children from 6 months of age and older,

-passive protection of infant(s) from birth to less than 6 months of age following vaccination of pregnant women (see Sections 4.4, 4.6 and 5.1).

The use of Quadrivalent Influenza Vaccine (split virion, inactivated) should be based on official recommendations.

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

העלון 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

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. Name of the medicinal product**

Vaxigrip Tetra, suspension for injection in pre-filled syringe  
Quadrivalent influenza vaccine (split virion, inactivated)

### **2. Qualitative and quantitative composition**

Influenza virus (inactivated, split) of the following strains\*:

A/Victoria/4897/2022 (H1N1)pdm09-like strain (A/Victoria/4897/2022, IVR-238)	15 micrograms HA**
A/ <del>Darwin</del> Thailand/ <del>89/2021-2022</del> (H3N2) - like strain (A/ <del>California</del> Darwin/ <del>9122/2021-2022</del> , <del>IVRSAN--228022</del> )	15 micrograms HA**
B/Austria/1359417/2021 - like strain (B/Michigan/01/2021, wild type).....	15 micrograms HA**
B/Phuket/3073/2013 - like strain (B/Phuket/3073/2013, wild type)	15 micrograms HA**
	Per 0.5 mL dose

\* propagated in fertilised hens' eggs from healthy chicken flocks

\*\* haemagglutinin

This vaccine complies with the WHO recommendations (Northern Hemisphere) and EU decision for the 2023-2024/2024-2025 season.

For the full list of excipients, see Section 6.1.

Vaxigrip Tetra may contain traces of eggs, such as ovalbumin, and of neomycin, formaldehyde and octoxinol-9, which are used during the manufacturing process (see Section 4.3).

[...]

### **~~7. Manufacturer~~**

~~SANOFI PASTEUR 14 Espace Henry Vallée 69007 Lyon FRANCE~~

### **8. Marketing Authorisation/Registration Hholder**

~~Sanofi Israel Ltd., Greenwork Park, P.O box 47, Yakum MEDICI MEDICAL LTD. 3  
Hamachshev St. Netanya 4250713, Israel~~

### **9. Marketing authorisation number**

160-19-35153-00

Revised in August 2023-2024 according to MoH guidelines.