

פרסום עדכון בעלוני התכשיר: FluMist**הרכב:**

Each pre-filled refrigerated FluMist sprayer contains a single 0.2 mL dose contains $10^{7.0 \pm 0.5}$ FFU (fluorescent focus units) of live attenuated influenza virus reassortants of each of the three strains:

A/ Missouri/11/2025 (H1N1)pdm09 - like strain (A/ Switzerland/6849/2025)

A/ Darwin/1454/2025 (H3N2) - like strain (A/ Darwin/1369/2025)

B/ Tokyo/EIS13-175/2025 - like strain (Perth/115/2025)

התוויה:

FluMist® is a vaccine indicated for active immunization for the prevention of influenza disease caused by influenza virus subtypes A and type B contained in the vaccine.

FluMist is approved for use in persons 2 through 49 years of age.

חברת אסטרזניקה ישראל מבקשת להודיע על עדכון עלון בהתאם להוראות משרד הבריאות בתאריך **אפריל 2026**.

העדכונים המהותיים בעלון לרופא הינם:**2. Qualitative and quantitative composition**

Each pre-filled refrigerated FluMist sprayer contains a single 0.2 mL dose. Each 0.2 mL dose contains $10^{7.0 \pm 0.5}$ FFU (fluorescent focus units) of live attenuated influenza virus reassortants of each of the three strains:

A/ [Missouri/11/2025](#)~~Victoria/4897/2022~~ (H1N1)pdm09 - like strain (A/

[Switzerland/6849/2025](#)~~Norway/31694/2022~~)

A/ [Darwin/1454/2025](#)~~Croatia/10136RV/2023~~ (H3N2) - like strain (A/ [Darwin/1369/2025](#)~~Perth/722/2024~~)

B/ [Tokyo/EIS13-175/2025](#)~~Austria/1359417/2021~~ - like strain ([Perth/115/2025](#)~~B/Austria/1359417/2021~~)

5.2 Administration Instructions

Each sprayer contains a single dose (0.2 mL) of FluMist; administer approximately one half of the contents of the single-dose intranasal sprayer into each nostril (~~each sprayer contains 0.2 mL of vaccine~~). Refer to Figure 1 for step-by-step administration instructions. Following

administration, dispose of the sprayer according to the standard procedures for medical waste (e.g., sharps container or biohazard container). Do not use FluMist if damaged, for example if the plunger is loose or displaced from the sprayer or if there are any signs of leakage.

12. DESCRIPTION

Each of the reassortant strains in FluMist express the HA and NA of wild- type viruses that are related to strains expected to circulate during the ~~2025~~2026-~~2026~~2027 influenza season. The viruses (A/H1N1, A/H3N2 and the B strain) have been recommended for inclusion in the annual trivalent influenza vaccine formulation.

Specific pathogen-free (SPF) eggs are inoculated with each of the reassortant strains and incubated to allow vaccine virus replication. The allantoic fluid of these eggs is harvested, pooled, and then clarified by filtration. The virus is concentrated by ultracentrifugation and diluted with stabilizing buffer to obtain the final sucrose and potassium phosphate concentrations. The viral harvests are then sterile filtered to produce the monovalent bulks. Each lot is tested for *ca*, *ts*, and *att* phenotypes and is also tested extensively by *in vitro* and *in vivo* methods to detect adventitious agents. Monovalent bulks from the three strains are subsequently blended and diluted as required to attain the desired potency with stabilizing buffers to produce the trivalent bulk vaccine. The bulk vaccine is then filled directly into individual sprayers for nasal administration.

Each pre-filled refrigerated FluMist sprayer contains a single 0.2 mL dose. Each 0.2 mL dose contains $10^{7.0 \pm 0.5}$ FFU (fluorescent focus units) of live attenuated influenza virus reassortants of each of the three strains:

A/ ~~Missouri/11/2025~~Victoria/4897/2022 (H1N1)pdm09 - like strain (A/
~~Switzerland/6849/2025~~Norway/31694/2022)

A/ ~~Darwin/1454/2025~~Croatia/10136RV/2023 (H3N2) - like strain
(~~Darwin/1369/2025~~A/Perth/722/2024)

B/ ~~Tokyo/EIS13-175/2025~~Austria/1359417/2021 - like strain (B/
~~Perth/115/2025~~Austria/1359417/2021)

16.1 How Supplied

FluMist is supplied in a single-dose (0.2mL) intranasal sprayer. ~~package of 1 or 10 pre-filled, single-dose (0.2 mL) intranasal sprayers~~. The single-use intranasal sprayer is not made with natural rubber latex.

Carton containing 1 intranasal sprayer.

Carton containing 10 intranasal sprayers.

העדכונים המהותיים בעלון לצרכן הינם:



הרכב:

כל 0.2 מ"ל תרסיס לאף מוכן לשימוש מכיל:

$10^{7.0 \pm 0.5}$ FFU (fluorescent focus units) of live attenuated influenza virus reassortants of each of the three strains for the ~~2026~~2026-2027-2025 season:

A/ Missouri/11/2025~~Victoria/4897/2022~~ (H1N1) pdm09 - like strain (A/

Switzerland/6849/2025~~Norway/31694/2022~~)

A/ Darwin/1454/2025~~Croatia/10136RV/2023~~ (H3N2) - like strain (A/ Darwin/1369/2025

Perth/722/2024)

B/ Tokyo/EIS13-175/2025~~Austria/1359417/2021~~ - like strain (B/

Perth/115/2025~~Austria/1359417/2021~~)

מקרא לעדכונים המסומנים:

תוספת טקסט מסומנת בקו תחתון

מחיקת טקסט מסומנת בקו חוצה

העדכונים מפורסמים במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלם מודפסים על ידי פניה לבעל הרישום.

בכבוד רב,

קארין קנבל דובסון
רוקחת ממונה
אסטרזהניקה (ישראל) בע"מ

אסטרזהניקה (ישראל) בע"מ, רח' עתירי ידע 1 כפר סבא 4464301

טלפון 073-2226099 פקס 09-7406527