

מרץ 2022

רופא/ה נכבד/ה

רוקח/ת נכבד/ה שלום רב,

פרסום עדכון בעלוני התכשיר: FluMist® Quadrivalent

הרכב:

Each pre-filled refrigerated FluMist Quadrivalent 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 four strains:

A/Victoria/2570/2019 (H1N1)pdm09 - like strain (A/Victoria/1/2020)

A/Darwin/9/2021 (H3N2) - like strain (A/Norway/16606/2021)

B/Austria/1359417/2021 - like strain (B/Austria/1359417/2021)

B/Phuket/3073/2013 - like strain (B/Phuket/3073/2013)

התוויה:

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

FluMist Quadrivalent 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 מרץ 2022.

העדכונים המהותיים בעלון לרופא הינם: 

2. Qualitative and quantitative composition

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A/Darwin/9/2021 (H3N2) - like strain (A/Norway/16606/2021)

~~A/Cambodia/e0826360/2020 (H3N2) - like strain (A/Tasmania/503/2020)~~

B/Austria/1359417/2021 - like strain (B/Austria/1359417/2021)

~~B/Washington/02/2019 - like strain (B/Washington/02/2019)~~

B/Phuket/3073/2013 - like strain (B/Phuket/3073/2013)

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10. DRUG INTERACTIONS

10.4 Concomitant Administration with Other Live Vaccines

Concomitant administration of the trivalent formulation of FluMist ~~Quadrivalent~~-with Measles, Mumps, and Rubella Virus Vaccine Live (MMR, manufactured by Merck & Co., Inc.) ~~or~~ and the Varicella ~~Virus~~ Vaccine Live (manufactured by Merck & Co., Inc.) ~~has not been studied. Concomitant administration of FluMist with MMR and the varicella vaccine~~ was studied in children 12 through 15 months of age [see *Clinical Studies (15.5)*]. Concomitant administration of ~~FluMist with~~ the MMR and the varicella vaccine with the trivalent or quadrivalent formulations has not been studied in children older than 15 months of age ~~has not been studied~~.

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12. DESCRIPTION

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Each of the reassortant strains in FluMist Quadrivalent express the HA and NA of wild- type viruses that are related to strains expected to circulate during the ~~2021-2022-2022-2023~~ influenza season. Three of the viruses (A/H1N1, A/H3N2 and one B strain) have been recommended for inclusion in the annual trivalent and quadrivalent influenza vaccine formulations. An additional B strain has been recommended by the USPHS for inclusion in the quadrivalent influenza vaccine formulation.

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B/Phuket/3073/2013 - like strain (B/Phuket/3073/2013)

העדכונים המהותיים בעלון לצרכן הינם:



הרכב:

כל 0.2 מ"ל ספריי לאף מוכן לשימוש מכיל:

$10^{7.0\pm 0.5}$ FFU (fluorescent focus units) of live attenuated influenza virus reassortants of each of the four strains for the ~~2021-2022-2022-2023~~ season:

A/Victoria/2570/2019 (H1N1)pdm09 - like strain (A/Victoria/1/2020)

A/Darwin/9/2021 (H3N2) - like strain (A/Norway/16606/2021)

~~A/Cambodia/e0826360/2020 (H3N2) - like strain (A/Tasmania/503/2020)~~

B/Phuket/3073/2013 - like strain (B/Phuket/3073/2013)

[B/Austria/1359417/2021 - like strain \(B/Austria/1359417/2021\)](#)

[B/Washington/02/2019—like strain \(B/Washington/02/2019\)](#)

מקרא לעדכונים המסומנים:

תוספת טקסט מהותי מסומנת בצבע אדום.
מחיקת טקסט מסומנת בקו חוצה בצבע כחול.

העלונים 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