

רופאה נכבדה

רוקחת נכבדה/ שלום רב,

פרסום עדכון בעלון התכשיר : FluMist Quadrivalent

הרכב:

Each pre-filled refrigerated FluMist Quadrivalent sprayer contains a single 0.2 mL dose. Each 0.2 mL dose contains $10^{6.5-7.5}$ FFU (fluorescent focus units) of live attenuated influenza virus reassortants of each of the four strains:

A/Guangdong-Maonan/SWL1536/2019 (H1N1)pdm09 - like strain (A/Hawaii/66/2019)
A/Hong Kong/2671/2019 (H3N2) - like strain (A/Hong Kong/2671/2019)
B/Washington/02/2019 - like strain (B/Washington/02/2019)
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 אסטרזהניקה ישראל מבקשת להודיע על עדכון עלון בהתאם להוראות משרד הבריאות בתאריך
יוני 2020

העדכונים המהותיים בעלון לרופא הם:

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~~A/Brisbane/02/2018 (H1N1)pdm09 – like strain (A/Switzerland/3330/2017), A/Kansas/14/2017 (H3N2) – like strain (A/Kansas/14/2017), B/Phuket/3073/2013 – like strain (B/Phuket/3073/2013), B/Colorado/06/2017 – like strain (B/Colorado/06/2017)~~
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12. DESCRIPTION

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 ~~2019-2020~~2020-2021 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)

Each 0.2 mL dose also contains 0.188 mg/dose monosodium glutamate, 2.00 mg/dose hydrolyzed porcine gelatin, 2.42 mg/dose arginine, 13.68 mg/dose sucrose, 2.26 mg/dose dibasic potassium phosphate, and 0.96 mg/dose monobasic potassium phosphate. Each dose contains residual amounts of ovalbumin (< 0.24 mcg/dose), and may also contain residual amounts of gentamicin sulfate (< 0.015 mcg/mL), and ethylenediaminetetraacetic acid (EDTA) (<~~2.30-37~~ mcg/dose). FluMist Quadrivalent contains no preservatives.

העדכונים המהותיים בעלון לצרכן הם:

הרכב

כל 0.2 מ"ל ספריי לאף מוכן לשימוש מכיל:

$10^{6.5-7.5}$ FFU (fluorescent focus units) of live attenuated influenza virus reassortants of each of the four strains for the ~~2019-2020~~2020-2021 season:

~~A/Brisbane/02/2018 (H1N1) pdm09 - like strain (A/Switzerland/3330/2017),~~

~~A/Kansas/14/2017 (H3N2) - like strain (A/Kansas/14/2017),~~

A/Guangdong-Maonan/SWL1536/2019 (H1N1)pdm09 - like strain (A/Hawaii/66/2019)

A/Hong Kong/2671/2019 (H3N2) - like strain (A/Hong Kong/2671/2019)

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

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

~~B/Colorado/06/2017 - like strain (B/Colorado/06/2017)~~

מקרא לעדכונים המסומנים

הוספת טקסט מהותי מסומנת בצבע. מחיקת טקסט מסומנת בקו חוצה

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

בכבוד רב,
קארין קנבל דובסון
רוקחת ממונה
אסטרזניקה (ישראל) בע"מ

אסטרזניקה (ישראל) בע"מ, ת.ד. 1455, הוד השרון 4524075

טלפון 09-7406528 פקס 09-7406527