יוני 2024

הנדון: AREXVY / ארקסווי

Respiratory Syncytial Virus (RSV) vaccine (recombinant, adjuvanted)

Powder and suspension for suspension for injection

רופא/ה נכבד/ה
רוקח/ת נכבד/ה,

חברת גלקסוסמיתקליין ישראל בע"מ (GSK) מבקשת להודיע על עדכון העלון לרופא של התכשיר AREXVY / ארקסווי.

המרכיב הפעיל וחוזקו:

Before reconstitution, the powder (antigen) vial contains:	
RSVPreF3[1] antigen	163 micrograms
After reconstitution, one dose (0.5 mL) contains:	
RSVPreF3[1] antigen	120 micrograms

[1] Respiratory Syncytial Virus recombinant glycoprotein F stabilised in the pre-fusion conformation = RSVPreF3

ההתוויה הרשומה לתכשיר בישראל:

Arexvy is indicated for active immunisation for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus in adults 60 years of age and older.

בהודעה זו מצויינים השינויים שבוצעו בעלון .
מקרא לעדכונים המסומנים:

תוספת – כתב כחול עם קו תחתון, מחיקה-כתב אדום עם קו מחיקה

להלן העידכונים שנעשו בעלון לרופא:

1. NAME OF THE MEDICINAL PRODUCT

AREXVY

Respiratory Syncytial Virus (RSV) vaccine (recombinant, adjuvanted)

4.4 Special warnings and precautions for use

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Prior to immunisation

Appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine. ~~Close observation for at least 15 minutes is recommended following vaccination.~~

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4.5 Interaction with other medicinal products and other forms of interaction

Use with other vaccines

Arexvy may be administered concomitantly with inactivated seasonal influenza vaccines ~~(quadrivalent,(~~ standard dose~~,~~ unadjuvanted~~, inactivated). In a randomised study in adults 60 years of age and older, the criteria for non-inferiority of the immune responses in the co-~~ high dose unadjuvanted, or standard dose adjuvanted).

Upon concomitant administration ~~versus the separate administration group were met. However However~~of Arexvy with seasonal influenza vaccines, numerically lower RSV A and B neutralising titres and numerically lower influenza A and B haemagglutination inhibition titres were observed ~~when Arexvy and inactivated seasonal influenza vaccine were co-administered than when they were administered separately. The clinical relevance of this finding is unknown. There are no data on co-administration with high dose or adjuvanted seasonal influenza vaccines.~~ as compared to the separate administration. This was not observed consistently across studies. The clinical relevance of these findings is unknown.

If Arexvy is to be given at the same time as another injectable vaccine, the vaccines should always be administered at different injection sites.

Concomitant administration of Arexvy with other vaccines than those listed above has not been studied.

6.1 List of excipients

Powder (RSVPreF3 antigen)

Trehalose dihydrate
Potassium dihydrogen phosphate
Dipotassium phosphate
Polysorbate 80

Suspension (AS01E Adjuvant System)

Sodium chloride
Potassium dihydrogen phosphate
Dioleoyl phosphatidylcholine
Disodium phosphate anhydrous
Cholesterol
3-O-desacyl-4'-monophosphoryl lipid A (MPL)
Purified Quillaja Saponin (QS-21)
Water for injection

למידע נוסף יש לעיין בעלון לרופא המעודכן.
העלון לרופא מצורף להודעה זו.
העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות:
ניתן לקבלו מודפס על-ידי https://www.old.health.gov.il/units/pharmacy/trufot/index.asp?safa=h
פניה לחברת גלקסוסמיתקליין רח' בזל 25 פתח תקוה בטלפון: 03-9297100.

בברכה,

ליליאנה בלטר
רוקחת ממונה