



אוגוסט 2021

הנדון: BEXSERO / בקסרו
Meningococcal group B Vaccine
Suspension for injection

רופא/ה נכבד/ה
רוקח/ת נכבד/ה,

חברת גלקסומיתקליין ישראל בע"מ (GSK) מבקשת להודיע על עדכון העלון לרופא של התכשיר BEXSERO / בקסרו.

בנוסף החברה מבקשת להודיע על עלון חדש לצרכן. עד כה לתכשיר היה עלון לרופא בלבד. עלון לצרכן זה יחליף את העלון לרופא שנמצא כעת בתוך אריזת התכשיר.

חומרים פעילים:

-Neisseria Meningitidis group B strain NZ98/254 (outer – membrane vesicles (OMV))	25 MCG
-Neisseria Meningitidis group B FHBP Fusion Protein	50 MCG
-Neisseria Meningitidis group B Nada Protein	50 MCG
-Neisseria Meningitidis group B NHBA Fusion Protein	50 MCG

ההתוויה הרשומה לתכשיר בישראל:

Bexsero is indicated for active immunization of individuals from 2 months of age and older against invasive meningococcal disease caused by Neisseria meningitidis group B.

בהודעה זו מצויינים השינויים המהותיים שבוצעו לעלון .

עדכון העלון כולל עדכון למשטר המינון.

מקרא לעדכונים המסומנים:

תוספת – כתב כחול

מחיקה-כתב אדום עם קו מחיקה

Section	Marked update																							
4.2 Posology and method of administration	<p data-bbox="395 174 919 201">Adolescents (from 11 years of age) and adults</p> <p data-bbox="395 228 450 250">.....</p> <p data-bbox="539 286 638 313"><u>Posology</u></p> <p data-bbox="539 344 874 371">Table 1: Summary of posology</p> <table border="1" data-bbox="528 394 1474 1469"> <thead> <tr> <th data-bbox="528 394 762 450">Age at first dose</th> <th data-bbox="767 394 1002 450">Primary Immunisation</th> <th data-bbox="1007 394 1241 450">Intervals between Primary Doses</th> <th data-bbox="1246 394 1474 450">Booster</th> </tr> </thead> <tbody> <tr> <td data-bbox="528 456 762 689" rowspan="2">Infants, 2 months to 5 months^a</td> <td data-bbox="767 456 1002 573">Three doses each of 0.5 ml</td> <td data-bbox="1007 456 1241 573">Not less than 1 month</td> <td data-bbox="1246 456 1474 689" rowspan="2">Yes, one dose between 12 and 15 months of age with an interval of at least 6 months between the primary series and booster dose ^{b,c}</td> </tr> <tr> <td data-bbox="767 580 1002 689"><u>Two doses each of 0.5 ml</u></td> <td data-bbox="1007 580 1241 689"><u>Not less than 2 months</u></td> </tr> <tr> <td data-bbox="528 696 762 891">infants, 6 months to 11 months</td> <td data-bbox="767 696 1002 891">Two doses each of 0.5 ml</td> <td data-bbox="1007 696 1241 891">Not less than 2 months</td> <td data-bbox="1246 696 1474 891">Yes, one dose in the second year of life with an interval of at least 2 months between the primary series and booster dose ^c</td> </tr> <tr> <td data-bbox="528 898 762 1055">children, 12 months to 23 months</td> <td data-bbox="767 898 1002 1055">Two doses each of 0.5 ml</td> <td data-bbox="1007 898 1241 1055">Not less than 2 months</td> <td data-bbox="1246 898 1474 1055">Yes, one dose with an interval of 12 months to 23 months between the primary series and booster dose ^c</td> </tr> <tr> <td data-bbox="528 1061 762 1240">Children, 2 years to 10 years</td> <td data-bbox="767 1061 1002 1240" rowspan="2">Two doses each of 0.5 ml Two doses each of 0.5 ml</td> <td data-bbox="1007 1061 1241 1240" rowspan="2">Not less than 1 month Not less than 1 month</td> <td data-bbox="1246 1061 1474 1240" rowspan="2"> <p data-bbox="1299 1061 1430 1122">Need not established^d</p> <p data-bbox="1299 1128 1430 1189">Need not established^d</p> <p data-bbox="1278 1196 1457 1469">^dA booster dose should be considered in individuals at continued risk of exposure to meningococcal disease, based on official recommendations ^d</p> </td> </tr> <tr> <td data-bbox="528 1247 762 1469">Adolescents (from 11 years) and adults*</td> </tr> </tbody> </table> <p data-bbox="395 1505 450 1527">.....</p>	Age at first dose	Primary Immunisation	Intervals between Primary Doses	Booster	Infants, 2 months to 5 months ^a	Three doses each of 0.5 ml	Not less than 1 month	Yes, one dose between 12 and 15 months of age with an interval of at least 6 months between the primary series and booster dose ^{b,c}	<u>Two doses each of 0.5 ml</u>	<u>Not less than 2 months</u>	infants, 6 months to 11 months	Two doses each of 0.5 ml	Not less than 2 months	Yes, one dose in the second year of life with an interval of at least 2 months between the primary series and booster dose ^c	children, 12 months to 23 months	Two doses each of 0.5 ml	Not less than 2 months	Yes, one dose with an interval of 12 months to 23 months between the primary series and booster dose ^c	Children, 2 years to 10 years	Two doses each of 0.5 ml Two doses each of 0.5 ml	Not less than 1 month Not less than 1 month	<p data-bbox="1299 1061 1430 1122">Need not established^d</p> <p data-bbox="1299 1128 1430 1189">Need not established^d</p> <p data-bbox="1278 1196 1457 1469">^dA booster dose should be considered in individuals at continued risk of exposure to meningococcal disease, based on official recommendations ^d</p>	Adolescents (from 11 years) and adults*
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קיימים עדכונים נוספים . למידע נוסף יש לעיין בעלון לרופא המעודכן.

העלונים לצרכן ולרופא מצורפים להודעה זו.

העלונים לצרכן ולרופא נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות:

לחברת גלקסומייתקליין רח' בזל 25 פתח תקוה בטלפון: 03-9297100. <https://www.old.health.gov.il/units/pharmacy/trufot/index.asp?safa=h> וניתן לקבלם מודפסים על-ידי פניה

בברכה,

ליליאנה בלטר
רוקחת ממונה