



פברואר 2020

הנדון: BEXSERO / בקסרו
Meningococcal group B Vaccine
Suspension for injection
עדכון עיקרי – עדכון מידע בסעיף משטר המינון

רופא/ה נכבד/ה
רוקח/ת נכבד/ה,

חברת גלקסוסמיתקליין ישראל בע"מ (GSK) מבקשת להודיע על עדכון העלון לרופא של התכשיר BEXSERO / בקסרו. עדכון עיקרי נעשה בסעיף משטר המינון.

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 .

מקרא לעדכונים המסומנים:
תוספת – כתב כחול
מחיקה-כתב אדום עם קו מחיקה

Section	Marked update																								
4.2 posology and administration	Table 1: Summary of posology																								
	<table border="1"> <thead> <tr> <th>Age Group at first dose</th> <th>Primary Immunisation</th> <th>Intervals between Primary Doses</th> <th>Booster</th> </tr> </thead> <tbody> <tr> <td>Infants, 2 months to 5 months^a</td> <td>Three doses each of 0.5 ml, with first dose given at 2 months of age^a</td> <td>Not less than 1 month</td> <td>Yes, one dose between 12 and 15 months <u>of age with an interval of at least 6 months between the primary series and booster dose</u> ^{b,c}</td> </tr> <tr> <td>Unvaccinated infants, 6 months to 11 months</td> <td>Two doses each of 0.5 ml</td> <td>Not less than 2 months</td> <td>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>Unvaccinated children, 12 months to 23 months</td> <td>Two doses each of 0.5 ml</td> <td>Not less than 2 months</td> <td>Yes, one dose with an interval of 12 months to 23 months between the primary series and booster dose ^c</td> </tr> <tr> <td>Children, 2 years to 10 years</td> <td>Two doses each of 0.5 ml</td> <td>Not less than 2 <u>1</u> monthss</td> <td>Need not established ^d</td> </tr> <tr> <td>Adolescents (from 11 years of age) and adults*</td> <td>Two doses each of 0.5 ml</td> <td>Not less than 1 month</td> <td>Need not established ^d</td> </tr> </tbody> </table>	Age Group at first dose	Primary Immunisation	Intervals between Primary Doses	Booster	Infants, 2 months to 5 months^a	Three doses each of 0.5 ml, with first dose given at 2 months of age^a	Not less than 1 month	Yes, one dose between 12 and 15 months <u>of age with an interval of at least 6 months between the primary series and booster dose</u> ^{b,c}	Unvaccinated 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	Unvaccinated 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	Not less than 2 <u>1</u> months s	Need not established ^d	Adolescents (from 11 years of age) and adults*	Two doses each of 0.5 ml	Not less than 1 month	Need not established ^d
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^a The first dose should be given at <u>no earlier than</u> 2 months of age. The safety and efficacy of Bexsero in infants less than 8 weeks of age has not yet been established. No data are available.																									
^b In case of delay, the booster should not be given later than 24 months <u>of age</u> .																									
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* There are no data in adults above 50 years of age.																									

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

בברכה,
ליליאנה בלטר
רוקחת ממונה