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ינואר 2020

רופא/ה, רוקח/ת נכבד/ה,

חברת פייזר שמחה להודיעך על תוספת התוויה למתן **NIMENRIX** <u>החל מגיל 6 שבועות</u>.

<u>המרכיב הפעיל:</u>

After reconstitution, 1 dose (0.5 ml) contains:

Neisseria meningitidis group A polysaccharide[1] 5micrograms
Neisseria meningitidis group C polysaccharide[1] 5micrograms
Neisseria meningitidis group W-135 polysaccharide[1] 5micrograms
Neisseria meningitidis group Y polysaccharide[1] 5micrograms

[1]conjugated to tetanus toxoid carrier protein 44micrograms

<u>Indicated for:</u>
Nimenrix is indicated for active immunisation of individuals from the age of 6 weeks against invasive meningococcal diseases caused by Neisseria meningitidis group A, C, W-135 and Y.

<u>להלן העדכונים העיקריים בעלון לרופא:</u>

4.2 Posology and method of administration

<u>Posology</u>

Nimenrix should be used in accordance with available official recommendations.

Primary immunisation:

Infants from 6 weeks to less than 6 months of age: two doses, each of 0.5 ml, should be administered with an interval of 2 months between doses.

Infants from 6 months of age, children, adolescents and adults: a single 0.5 mL dose should be administered.
An additional primary dose of Nimenrix may be considered appropriate for some individuals (see section 4.4).

Booster doses
After completion of the primary immunisation course in infants 6 weeks to less than 12 months of age, a booster dose should be given at 12 months of age with an interval of at least 2 months after the last Nimenrix vaccination (see section 5.1).

In previously vaccinated individuals 12 months of age and older, Nimenrix may be given as a booster dose if they have received primary vaccination with a conjugated or plain polysaccharide meningococcal vaccine (see sections 4.4 and 5.1).

<u>Method of administration</u>

Immunisation should be carried out by intramuscular injection only. In infants, the recommended injection site is the anterolateral aspect of the thigh. In individuals from 1 year of age, the recommended injection site is the anterolateral aspect of the thigh or the deltoid muscle (see sections 4.4 and 4.5).

For instructions on reconstitution of the medicinal product before administration, see section 6.6.

4.4 Special warnings and precautions for use

Immune response in infants aged 6 months to less than 12 months
A single dose administered at 6 months was associated with lower human complement serum bactericidal assay (hSBA) titres to groups W-135 and Y compared with three doses administered at 2, 4, and 6 months (see section 5.1). The clinical relevance of this finding is unknown. If an infant aged 6 months to less than 12 months of age is expected to be at particular risk of invasive meningococcal disease due to exposure to groups W-135 and Y, consideration may be given to administering a second primary dose of Nimenrix after an interval of 2 months.

4.5 Interaction with other medicinal products and other forms of interaction

In infants, Nimenrix can be given concomitantly with combined DTaP-HBV-IPV/Hib vaccines and with 10-valent pneumococcal conjugate vaccine.

4.8 Undesirable effects

Data from a study in infants aged 6 to 12 weeks at the time of the first dose (Study MenACWY-TT-083), 1,052 subjects received at least one dose of a primary series of 2 or 3 doses of Nimenrix and 1,008 received a booster dose at approximately 12 months of age.

- Safety data have also been evaluated in a separate study, in which a single dose of Nimenrix was administered to 274 individuals aged 56 years and older.

Local and general adverse reactions
In the 6-12 weeks and in the 12-14 months age groups who received 2 doses of Nimenrix given 2 months apart, the first and second doses were associated with similar local and systemic reactogenicity.

5.1 Pharmacodynamic properties

See attached laeflet.

בנוסף, אושר עלון לצרכן המצורף להודעה זו.

השינויים המודגשים ברקע צהוב מהווים החמרה. כמו כן, בוצעו שינויים נוספים הכוללים תוספת מידע, השמטת מידע ועדכוני נוסח שאינם מהווים החמרה.

העלון המעודכן נשלח למשרד הבריאות לצורך פרסומו במאגר התרופות שבאתר משרד הבריאות:
https://www.old.health.gov.il/units/pharmacy/trufot/index.asp?safa=h

לחילופין, לקבלת עלונים מלאים מודפסים ניתן לפנות לחברת פייזר פרמצבטיקה ישראל בע"מ
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