ינואר 2020

הנדון: Engerix B 10mcg & 20mcg
Suspension for injection

רופא/ה נכבד/ה
רוקח/ת נכבד/ה,

חברת גלקסוסמיתקליין ישראל בע"מ (GSK) מבקשת להודיע:

-עדכון העלון לרופא של התכשיר Engerix B 10mcg & 20mcg - כולל עדכון נוסח התוויה ומשטר מינון
- עלון לצרכן חדש עבור התכשיר Engerix B 10mcg & 20mcg.

חומרים פעילים:

Engerix B 10mcg: HEPATITIS B VACCINES	10 mcg/0.5ml
Engerix B 20mcg: HEPATITIS B VACCINES	20 mcg/1ml

נבקש לעדכן כי התווית התכשיר עודכנה.
ההתוויה העדכנית המאושרת לתכשיר בישראל:

Engerix B is indicated for active immunisation against hepatitis B virus infection (HBV) caused by all known subtypes in non immune subjects . The 20µg dose vaccine in 1.0 ml suspension is intended for use in subjects 16 years of age and above. The 10 µg dose vaccine in 0.5 ml suspension is intended for use in subjects up to and including 15 years of age, including neonates. The categories within the population to be immunised are determined on the basis of official recommendations.
It can be expected that hepatitis D will also be prevented by immunisation with Engerix B as hepatitis D (caused by the delta agent) does not occur in the absence of hepatitis B infection.

בהודעה זו מצויינים השינויים המהותיים שבוצעו לעלון לרופא.

מקרא לעדכונים המסומנים:
תוספת – כתב כחול
מחיקה-כתב אדום עם קו מחיקה
טקסט שזז מקום-כתב ירוק

להלן העידכונים המהותיים שנעשו בעלון לרופא:

Section	Marked update
4.1 Therapeutic indications	Engerix B is indicated for active immunisation against hepatitis B virus infection (HBV) caused by all known subtypes in non immune subjects . The 20 µg dose vaccine in 1.0 ml suspension is intended for use in subjects 16 years of age and above. The 10 µg dose vaccine in 0.5 ml suspension is intended for use in subjects up to and including 15 years of age, including neonates. The categories within the population to be immunised are determined on the basis of official recommendations. It can be expected that hepatitis D will also be prevented by immunisation with Engerix B as hepatitis D (caused by the delta agent) does not occur in the absence of hepatitis B infection.
4.2 Posology and method of administration	*Posology* *Dosage* ~~***20 µg dose vaccine:***~~ The 20 µg dose vaccine in 1.0 ml suspension is intended for use in subjects 16 years of age and above.

~~***10 µg dose vaccine:***~~ The 10 µg dose vaccine in 0.5 ml suspension is intended for use in subjects up to and including 15 years of age, including neonates.

~~In children aged 10 to 15 years, the adult dose of 20 µg can be employed if low compliance is anticipated, since a higher percentage of vaccinees with protective antibody levels (≥ 10 IU/l) is obtained after two injections at this dosage~~
However, the 20 µg vaccine can also be used in subjects from 11 years up to and including 15 years of age as a 2-dose schedule in situations when there is a low risk of hepatitis B infection during the vaccination course, and when compliance with the complete vaccination course can be assured (see below and section 5.1).

Primary Immunisation schedules

~~All subjects:~~Subjects up to and including 15 years of age:

Two primary immunisation schedules can be recommended:

A 0, 1, 6 months schedule which gives optimal protection at month 7 and produces high antibody concentrations.

An accelerated schedule, with immunisation at 0, 1 and 2 months, which will confer protection more quickly and is expected to provide better patient compliance. With this schedule, a fourth dose should be administered at 12 months to assure long term protection as antibody concentrations after the third dose are lower than those obtained after the 0,1, 6 months schedule. In infants this schedule will allow for simultaneous administration of hepatitis B with other childhood vaccines.

Patients with renal insufficiency including patients undergoing haemodialysis, up to and including 15 years of age:

Patients with renal insufficiency, including patients undergoing haemodialysis, have a reduced immune response to hepatitis B vaccines. Either the 0, 1, 2 and 12 months or the 0, 1, 6 months schedule of Engerix B (10 µg) can be used. Based on adult experience, vaccination with a higher dosage of antigen may improve the immune response. Consideration should be given to serological testing following vaccination. Additional doses of vaccine may be needed to ensure a protective anti-HBs level ≥ 10 IU/l.

Neonates born of mothers who are HBV carriers:

The immunisation with Engerix B (10 mcg) of these neonates should start at birth, and two immunisation schedules have been followed. Either the 0, 1, 2 and 12 months or the 0, 1 and 6 months schedule can be used; however, the former schedule provides a more rapid immune response. When available , hepatitis B immune globulins (HBIg) should be given simultaneously with Engerix B at a separate injection site as this may increase the protective efficacy

Subjects from 11 years up to and including 15 years of age:

The 20 µg/1 ml vaccine may be administered in subjects from 11 years up to and including 15 years of age according to a 0, 6 months schedule. However, in this case, protection against hepatitis B infections may not be obtained until after the second dose (see section 5.1). Therefore, this schedule should be used only when there is a low risk of hepatitis B infection during the vaccination course and when completion of the two-dose vaccination course can be assured. If both conditions cannot be assured (for instance patients undergoing haemodialysis, travellers to endemic regions and close contacts of infected subjects), the three dose or the accelerated schedule of the 10 µg/0.5 ml vaccine should be used.

Subjects 16 years of age and above:

Two primary immunisation schedules can be recommended:

A 0, 1, 6 months schedule which gives optimal protection at month 7 and produces high antibody concentrations.

An accelerated schedule, with immunisation at 0, 1 and 2 months, which will confer protection more quickly and is expected to provide better patient compliance. With this schedule, a fourth dose should be administered at 12 months to assure long term protection as antibody concentrations after the third dose are lower than those obtained with the 0, 1, 6 months schedule.

Subjects 18 years of age and above:

In exceptional circumstances in adults, where an even more rapid induction of protection is required, e.g. persons travelling to areas of high endemicity and who commence a course of vaccination against hepatitis B within one month prior to departure, a schedule of three intramuscular injections given at 0, 7 and 21 days may be used. When this schedule is applied, a fourth dose is recommended 12 months after the first dose.

Patients with renal insufficiency including patients undergoing haemodialysis, 16 years of age and above:

The primary immunisation schedule for patients, with renal insufficiency including patients undergoing haemodialysis is four double doses (2 x 20 µg) at elected date, 1 month, 2 months and 6 months from the date of the first dose. The immunisation schedule should be adapted in order to ensure that the anti-HBs antibody concentrations remain equal to or higher than the accepted protective level of 10 IU/l.

~~- Patients with renal insufficiency including patients undergoing haemodialysis, up to and including 15 years of age,including neonates:~~

~~Patients with renal insufficiency, including patients undergoing haemodialysis, have a reduced immune response to hepatitis B vaccines. Either the 0, 1, 2 and 12 months or the 0, 1, 6 months schedule of Engerix B (10 µg) can be used. Based on adult experience, vaccination with a higher dosage of antigen may improve the immune response. Consideration should be given to serological testing following vaccination. Additional doses of vaccine may be needed to ensure a protective anti-HBs level ≥ 10 IU/l.~~

Known or presumed exposure to HBV:

In circumstances where exposure to HBV has recently occurred (eg needlestick with contaminated needle) the first dose of Engerix B can be administered simultaneously with HBIg which, however, must be given at a separate injection site (see section 4.5). The 0, 1, 2-12 months immunisation schedule should be advised.

Subjects up to and including 15 years of age:

~~- Neonates born of mothers who are HBV carriers:~~

~~The immunisation with Engerix B 10 mcg of these neonates should start at birth, and two immunisation schedules have been followed. Either the 0, 1, 2 and 12 months or the 0, 1 and 6 months schedule can be used; however, the former schedule provides a more rapid immune response. When available, hepatitis B immune globulins (HBIg) should be given simultaneously with Engerix B 10 mcg at a separate injection site as this may increase the protective efficacy.~~

These immunisation schedules may be adjusted to accommodate local immunisation practices with regard to the recommended age of administration of other childhood vaccines.

Subjects 16 years of age and above:

	These immunisation schedules may be adjusted to accommodate local immunisation practices. *Booster dose* Current data do not support the need for booster vaccination among immunocompetent subjects who have responded to a full primary vaccination course (Lancet 2000, 355:561). However, in immunocompromised subjects (eg subjects with chronic renal failure, haemodialysis patients, HIV positive subjects), boosters should be administered to maintain anti-HBs antibody concentrations equal or higher than the accepted protective level of 10 IU/l. For these immunocompromised subjects, post-vaccination testing every 6-12 months is advised. National recommendations on booster vaccination should be considered. *Interchangeability of hepatitis B vaccines* See section 4.5.

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

בברכה,
ליליאנה בלטר
רוקחת ממונה