נובמבר 2024

הנדון:
<u>הבריקס 720 ג'וניור, Havrix 720 Junior</u>
<u>הבריקס 1440, Havrix 1440</u>

רופא/ה נכבד/ה
רוקח/ת נכבד/ה,
חברת גלקסוסמיתקליין ישראל בע"מ (GSK) מבקשת להודיע על מעבר מדינת ייחוס עבור העלון לרופא של שני מינוני התכשיר- Havrix.

בהודעה זו מסומן רק המידע שמהווה החמרה לעומת העלון המאושר הקודם.

מרכיבים פעילים וחוזקם:
<u>Havrix 720 Junior</u>: Hepatitis A virus antigen, inactivated, 1440 E.L.U/ML
<u>Havrix 1440</u>: Hepatitis A virus antigen, inactivated, 720 E.L.U/ 0.5ML

ההתוויה המאושרת ע"י משרד הבריאות:

<u>Havrix 720 Junior</u>:
Active immunisation against HAV infection from 1 year up to and including 15 years of age.
The vaccine is particularly indicated for those at increased risk of infection or transmission.
It is also indicated for use during outbreaks of hepatitis A infection.

<u>Havrix 1440</u>:
Active immunisation against infections caused by Hepatitis A virus.
The vaccine is particularly indicated for those at increased risk of infection or transmission.

מקרא לעדכונים המסומנים:
- מידע שהוסר – מסומן בקו אדום חוצה ~~XXX~~
- תוספת – כתב כחול
- תוספת החמרה - מסומן בצהוב מרקר
- שינוי מיקום טקסט- כתב ירוק

<u>עדכונים מהותיים נעשו בסעיפים הבאים בעלון לרופא</u>:

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1 or to neomycin or to formaldehyde.
Hypersensitivity after previous administration of any hepatitis A vaccine.

4.4 Special warnings and precautions for use

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As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic event following the administration of the vaccine.
Close observation for at least 15 minutes is recommended following vaccination.

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Havrix will not prevent hepatitis infection caused by other agents such as hepatitis B virus, hepatitis C virus, hepatitis E virus or other pathogens known to infect the liver.

Individuals may be in the incubation period of a hepatitis A infection at the time of vaccination. It is not known whether Havrix will prevent hepatitis A in such cases.

As with any vaccine, a protective immune response may not be elicited in all vaccinees.

The immune response to Havrix could be impaired in immunocompromised individuals. Those individuals always require administration of a 2-dose vaccination schedule.

Havrix should be administered with caution to individuals with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration to them. Exceptionally and if in accordance with official recommendations, the vaccine may be administered subcutaneously to these individuals. However, this route of administration may lead to suboptimal anti-HAV antibody response. With both routes of administration, firm pressure should be applied to the injection site (without rubbing) for at least two minutes post injection.

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4.5 Interaction with other medicinal products and other forms of interaction

Since Havrix is an inactivated vaccine, its concomitant use with other inactivated vaccines is unlikely to result in interference with the immune responses.

Havrix can be given concomitantly with any of the following vaccines: typhoid, yellow fever, cholera (injectable), tetanus or with monovalent and combination vaccines comprised of measles, mumps, rubella and varicella.

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4.6 Fertility, pregnancy and lactation

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Breast-feeding

It is unknown whether Havrix is excreted in human milk. Although the risk can be considered as negligible, Havrix should be used during breast-feeding only when clearly needed.

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4.8 Undesirable effects

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Post-marketing data

The following additional adverse reactions have been identified during post-marketing surveillance with both Havrix 720 Junior and Havrix 1440 Adult.

System organ class	Frequency	Adverse reactions
Immune system disorders	Rare	Anaphylaxis, allergic reactions including anaphylactoid reactions and serum sickness-like reaction
Nervous system disorders	Rare	Convulsions
Vascular disorders	Rare	Vasculitis
Skin and subcutaneous tissue disorders	Rare	Angioneurotic oedema, erythema multiforme, urticaria

Musculoskeletal and connective tissue disorders	Rare	Arthralgia

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות:

https://data.health.gov.il/Drugs/index.html#!/byDrug וניתן לקבלם מודפסים על-ידי פניה לחברת גלקסוסמיתקליין רח' בזל 25 פתח תקוה בטלפון: 03-9297100.

בברכה,

אביטל רוזנצויג

רוקחת ממונה