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Dear Healthcare Professional

Supply of Engerix-B paediatric vaccine 10 mcg/0.5ml (Hepatitis B vaccine) – Australian pack

Batch Number: AHBVC861AR **Expiry Date: February 2022**
Batch Number: AHBVC950AX **Expiry Date: April 2023**

This communication is intended for Healthcare Professionals who administer the *Engerix-B paediatric* vaccine to patients.

- GSK has sourced supply of the Australian pack of *Engerix-B paediatric* vaccine upon request from PHARMAC to provide a paediatric form of the Hepatitis B vaccine to the New Zealand market.
- *Engerix-B paediatric* vaccine (10 mcg/0.5ml) is registered in New Zealand however there are some differences between the Australian Product Information provided in the Australian pack and the New Zealand Data Sheet.
- **The recommendations in the New Zealand Data Sheet should be followed when administering *Engerix-B paediatric* vaccine.**
- The *Engerix-B and Engerix-B paediatric* and New Zealand Data Sheet can be found at the following link: https://medsafe.govt.nz/profs/Datasheet/e/Engerix-Binj.pdf
- Key information on the dose and schedule stated within the *Engerix-B* New Zealand Data Sheet is attached.

Note: *Engerix-B* adult vaccine (20 mcg/1.0ml) is not affected and will continue to be supplied with the New Zealand Data Sheet.

Adverse event reporting to GSK and MEDSAFE:
In New Zealand, suspected adverse events should be reported to Medsafe via routes outlined at https://medsafe.govt.nz/safety/report-a-problem.asp**.** Should you become aware of an adverse event involving *Engerix-B* or *Engerix-B paediatric vaccine*, we encourage you to also report this to GSK Medical Information on 0800 808 500.

Medical Information:
Medical enquiries for GSK products can be directed to GSK Medical Information on 0800 808 500.

The New Zealand National Poisons Centre (0800 764 766) provide advice on the management of overdose.

Action required by Healthcare Professionals
Please share this information with other health care personnel involved in the administration of *Engerix-B paediatric* vaccine. For further information on Hepatitis B and vaccine recommendations, please refer to The New Zealand Immunisation Handbook (https://www.health.govt.nz/our-work/immunisation-handbook-2020/8-hepatitis-b).

Yours sincerely,

Brett Marett
Country Medical Director
GlaxoSmithKline NZ Limited

Dose and vaccination schedule information from New Zealand Data Sheet of *Engerix-B* 20 mcg/1.0ml and *Engerix-B paediatric* 10 mcg/0.5ml

Dose
The vaccine can be administered at any age from birth onwards.

Adults and adolescents over 15 years:
A dose of 20 µg of antigen protein in 1 mL suspension is recommended.

Adolescents:
In adolescents from the age of 10 years, and up to and including 15 years, a 10 µg dose can be recommended provided the immunisation is carried out in the 0, 1 and 6 months schedule, in circumstances which will ensure compliance to the full vaccination course. If compliance cannot be assured, then a 20 µg dose should be used to increase the proportion of subjects protected after the first and second doses.

Neonates, infants and younger children:
A dose of 10 µg of antigen protein in 0.5 mL suspension is recommended for neonates, infants and children up to 10 years of age although a dose of 20 µg may also be used when a paediatric presentation is not available. In neonates and infants, maternally transferred antibodies do not interfere with the active immune response to the vaccine.

Vaccination Schedule:
It is suggested that in conjunction with the *ENGERIX-B* vaccination schedule recommendations, the New Zealand Ministry of Health Immunisation Guidelines* on hepatitis B be consulted prior to use of the vaccine.

Primary vaccination:
This consists of three intramuscular doses of vaccine according to either of three different schedules.
In areas of low risk of infection:
• 1st dose: At elected date
• 2nd dose: 1 month later
• 3rd dose: 6 months from the date of the first dose.

In areas of high risk of infection:
• 1st dose: At elected date
• 2nd dose: 1 month later
• 3rd dose: 2 months from the date of the first dose.

Use in exceptional circumstances in adults (e.g. travellers commencing hepatitis B primary vaccination within one month of departure):
• 1st dose: At elected date
• 2nd dose: 7 days later
• 3rd dose: 21 days from the date of the first dose.

The two accelerated vaccination schedules of 0, 1 and 2 months or 0, 7 and 21 days may be used in circumstances where more rapid protection is required (e.g. contacts of carriers, and immunisation of travellers). However, as higher seroprotective rates are observed following the 0, 1, 2 month schedule, it is recommended the 0, 7, 21 day schedule be administered only in exceptional circumstances (e.g. travellers commencing hepatitis B primary vaccination within one month of departure). Since the peak antibody levels reached after these shorter schedules of primary vaccination are lower compared to the 0, 1 and 6 month schedule, it is recommended that a fourth dose (booster) be given at 12 months after the first dose of vaccine. A 20 µg dose should be used with these accelerated schedules.

Booster Dose
Until now, it is not known whether individuals who have responded to the vaccine will require booster doses to ensure long term protection or whether natural boosting without symptoms and chronic infection will occur when vaccinees with anti-HBs titers below the protective level of 10 IU/L are exposed to virus. Until such time as there is sufficient evidence to clarify the situation, it would seem wise to recommend a booster dose when the anti-HBs level falls below 10 IU/L. The timing for a booster dose will depend upon the anti-HBs level reached after the primary course of vaccination. From available data the following general recommendations for the booster can be made:

1. After 0, 1, 6 month primary vaccination schedule. A booster dose after this primary course of vaccination will, on average, probably not be required earlier than five years later.

2. After 0, 1, 2 month or 0, 7, 21 day primary vaccination schedule. Since the peak antibody levels reached after these shorter schedules of primary vaccination are lower (compared to the 0, 1 6 month schedule), it is recommended that a booster dose be given at 12 months after the first dose of vaccine. The next booster will probably not be required before another eight years.

Neonates born to HBV carrier mothers
The recommended treatment regimen for infants born to HBsAg+ and HBsAg+/eAg+ mothers is as follows:
Dose: 10 ug/0.5 mL at birth, then 1 month and either 2 or 6 months after the first dose. Hepatitis B immunoglobulin (HBIG) 100IU is given at birth.
Infants born to HBsAg+ and HBsAg+/eAg+ mothers may be administered either a 0, 1, 2 month or 0, 1, 6 month primary schedule, however the 0, 1, 2 month schedule elicits a more rapid immune response. The first dose of vaccine and immunoglobulin should be given within 24 hours of birth at separate sites.
Testing for HBsAg and anti-HBs is suggested at 12-15 months of age. If HBsAg is not detectable and anti-HBs is present, the child has been protected.

Immunocompromised Patients
The basic vaccination course recommended for chronic haemodialysis patients and other subjects who have an impairment of their immune system is four doses of 40 µg according to the following schedule:
• 1st dose: at elected date
• 2nd dose: 1 month later
• 3rd dose: 2 months from the date of the first dose.
• 4th dose: 6 months from the date of the first dose.
The anti-HBs titer of such patients should be checked annually and a booster dose recommended when it is close to the protective level of 10 IU/L. ENGERIX-B booster doses of 40 µg (2 x 20 µg) are recommended.

Post-Exposure Prophylaxis
There are no adequately controlled studies on the effectiveness of hepatitis B immunoglobulin administration, along with the vaccine, in adults and older children exposed to hepatitis B virus through 1) needlestick, ocular or mucous membrane exposure to blood known or presumed to contain HBsAg; 2) human bites by known or presumed HBsAg carriers that penetrate the skin; 3) following intimate sexual contact with known or presumed HBsAg carriers.
Hepatitis B immunoglobulin (human) (400 IU for adults) should be given intramuscularly as soon as possible, preferably within 24 hours of exposure. *ENGERIX-B* should be given at a separate site within 7 days and then at 1 month.

For the full *Engerix-B paediatric* and *Engerix-B* Data Sheet, refer to https://medsafe.govt.nz/profs/Datasheet/e/Engerix-Binj.pdf