Product: Hepatitis A Vaccine (Inactivated, Adsorbed) (Avaxim 80)
Strength: 0.5 mL Suspension for Intramuscular Injection
Presentation: 0.5 mL Type 1 pre-filled glass syringe with or without heat marker (Box of 1's)
I: Hepatitis A Vaccine (Inactivated, Adsorbed) –Indicated for children ages 12 months to 15 years against the infection caused by the hepatitis A virus.
C: Hypersensitivity to the active substance, to any of the excipients, to neomycin which may be present in traces owing to their use during the manufacturing process. Vaccination should be postponed in case of severe acute febrile disease.
W/P: Syncope can occur following, or even before, any vaccination as a psychogenic response to the needle injection, especially in adolescents. This may be accompanied by several neurological signs such as transient sight disorders, paraesthesia and tonic-clonic limb movements during the recovery phase. It is important that procedures be in place to avoid any injury from faints. It is recommended to wait for the end of an immunosuppressive treatment before vaccinating or to make sure the subject is well protected. Because of the incubation period of hepatitis A, infection may already be present, although asymptomatic, at the time of vaccination. The effect of administering Avaxim 80 during the incubation period of hepatitis A has not been documented. The use of this vaccine in subjects with liver disease should be considered with caution, as no studies have been performed in such subjects. The vaccine does not protect against infection caused by hepatitis B virus, hepatitis C virus, hepatitis E virus or by other known liver pathogens. Avaxim 80 contains 10 micrograms of phenylalanine in each 0.5 mL dose, which is equivalent to 0.17 micrograms/kg for a 60 kg person. Phenylalanine may be harmful for people with phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.
Interactions: The simultaneous administration of immunoglobulins with this vaccine in two different injection sites may be performed. In case of simultaneous administration, this vaccine must not be mixed with other vaccines in the same syringe. The vaccine may be administered simultaneously, in two different injection sites, with the routine booster vaccine of the child during the second year of life i.e., various vaccines containing one or more of following valences: diphtheria, tetanus, pertussis (acellular or whole cells), *Haemophilus influenzae* of type b and inactivated or oral poliomyelitis. This vaccine can be administered simultaneously, but at two different injection sites, with a vaccine against measles, mumps and rubella. This vaccine can be used as a booster in subjects previously vaccinated with another inactivated Hepatitis A vaccine.
AE: Decrease in appetite, Irritability, Insomnia, Headache, Diarrhea, Nausea, Vomitting, Fever, Fatigue, Redness, Swelling and Pain on the injection site
PK/ PD: Avaxim 80 is prepared from hepatitis A virus cultured, harvested, purified and then inactivated by formaldehyde. It confers immunity against hepatitis A virus (HAV) by inducing anti-HAV antibody titres longer lasting and higher than those obtained after passive immunization with immunoglobulins. This vaccine has been demonstrated to elicit protective anti-HAV antibody titres (≥20 mIU/mL) within two weeks following the injection in over 95% of individuals and in 100% of individuals before the booster dose administered 6 months after the first dose. A study conducted in Argentina (an area of intermediate endemicity for hepatis A) enabled the evaluation of long-term persistence of anti-HAV antibodies in children aged 12 months to 47 months vaccinated with 2 doses of Avaxim 80 U Pediatric 6 months apart. The results show a persistence of the antibodies until 14–15 years at levels considered as protective and do not suggest the need for new administration of the vaccine. A mathematical model using the available data from this study until 14–15 years after administration of the 2 doses of Avaxim 80 U Pediatric predicts a persistence of the protective anti-HAV antibodies for at least 30 years in 87.5% (CI 95%: 74.1; 94.8) of these children.

References:
Hepatitis A Vaccine (Inactivated, Adsorbed) (Avaxim 80).Philippines Prescribing Information
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