



## VACCINE: HEPATITIS B



### 1. Vaccine Indication

Hepatitis B vaccine is indicated for the primary prevention of hepatitis B in persons not previously infected with the hepatitis B virus (HBV).

### 2. Rationale for vaccination

The primary objective of hepatitis B immunisation is to prevent infection with HBV, and thereby prevent:

- Perinatal and early childhood HBV transmission
- Chronic hepatitis B, which is acquired mainly in childhood
- Chronic liver disease
- Cirrhosis and hepatocellular carcinoma

### 3. Types of vaccines

There are two types of hepatitis B vaccines:

- **Recombinant or genetically engineered vaccines** are produced by inserting a gene that codes for hepatitis B surface antigen (HBsAg) into a plasmid, which is then propagated in yeast or mammalian cells. The HBsAg produced by yeast or mammalian cells is then highly purified and used as a vaccine.
- **Plasma-derived vaccines** are prepared by purifying HBsAg particles from the plasma of hepatitis B chronic carriers. The particles are highly purified, inactivated, and then used as vaccines.

### 4. Composition of the vaccine

Hepatitis B vaccine contains the hepatitis B surface antigen (HBsAg), which makes up part of the outer envelope membrane of the virus.

### 5. Immunogenicity of vaccines

Following immunisation with 3 doses of the hepatitis B vaccine, the individual develops antibodies against HBsAg, called anti-HBs. The development of detectable levels of anti-HBs is known as seroconversion, and levels must rise to at least 10mIU/ml for the individual to be protected. This state is called seroprotection.

Generally, more than 95% of children and adolescents, and more than 90% of adults develop protective levels of anti-HBs after the administration of the recommended three doses. Studies conducted on the immunogenicity of hepatitis B vaccines in children vaccinated in the EPI-SA have found protection rates of between 93% and 97.8%, while clinical trials have shown seroprotection rates of between 95% and 100%. Vaccination of immunocompromised individuals and haemodialysis patients often requires more doses as these individuals respond poorly to the standard vaccination schedule.

## **6. Efficacy and long-term protection**

Current real time data indicate that most vaccinated individuals (children and adults) remain protected from hepatitis B disease for at least 20 years. These data are based on the studies conducted from the first hepatitis B vaccines which became available in the early 1980's. Although some individuals may lose protective anti-HBs (i.e. equal or greater than 10 mIU/ml) over time, they remain protected from the disease by the immunologic memory cells of the immune system which produce an anamnestic response upon re-exposure.

## **7. Integration of hepatitis B vaccine into the South African Expanded Programme on Immunisation**

Hepatitis B vaccine was introduced into the EPI-SA on 1st April 1995, as a three dose schedule vaccine administered at the same time as DTP.

## **8. Candidates for vaccination**

In South Africa, hepatitis B vaccine is given to babies at 6, 10, and 14 weeks of life as part of the EPI-SA schedule. Infants with HIV infection should be vaccinated within the EPI schedule.

In addition, the following persons are at substantial risk of HBV infection and should be vaccinated:

- persons with occupational risks such as health care and public safety workers
- neonates born to hepatitis B chronic carrier mothers
- household contacts of hepatitis B chronic carriers
- sex partners of hepatitis B chronic carriers
- people with more than one sexual partner
- people with history of a sexually transmitted disease
- injection drug users and haemodialysis patients
- recipients of blood products such as haemophiliacs
- inmates of long-term correctional facilities
- clients and staff of institutions for developmentally disabled individuals
- HIV infected individuals
- travellers to hepatitis B endemic areas.

## **9. Vaccination regimen and route of administration**

Hepatitis B vaccine is given in 3 separate doses by intramuscular injection in the anterolateral aspect of the thigh for infants, or the deltoid muscle for older children and adults. It can be safely given on the same day as other EPI vaccines. If hepatitis B vaccine is to be administered as a monovalent dose and on the same day as other injectable vaccines, the vaccines should preferably be given at different sites.

## **10. Interchangeability of vaccines**

Vaccines of different types (recombinant or plasma-derived) can be used interchangeably to complete a vaccination course.

## **11. Does hepatitis B vaccine protect against other forms of viral hepatitis?**

Hepatitis B vaccine only protects against hepatitis B, it does not offer protection against hepatitis caused by other viruses and agents.

## **12. Side effects and special precautions**

Hepatitis B vaccine is highly safe. Mild side-effects include soreness at the injection site, fatigue, irritability, headache and fever. Persons who are allergic to yeast-derived products should not be given the yeast-derived vaccine; they should be given the plasma-derived vaccine. Persons who reacted negatively to a previous dose of the vaccine should not be vaccinated.

### **Where to find us:**

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