PRODUCT INFORMATION

COMVAX®

[Haemophilus b Conjugate (Meningococcal Protein Conjugate) and Hepatitis B (Recombinant) Vaccine]

NAME OF THE DRUG

[Haemophilus b Conjugate (Meningococcal Protein Conjugate) and Hepatitis B (Recombinant) Vaccine]

DESCRIPTION

COMVAX is a sterile bivalent vaccine made of the antigenic components used in producing PedvaxHIB [Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate)] and H-B-VAX II [Hepatitis B Vaccine (Recombinant)]. These components are the Haemophilus influenzae type b capsular polysaccharide (PRP) that is covalently bound to an outer membrane protein complex (OMPC) of Neisseria meningitidis and hepatitis B surface antigen (HBsAg) from recombinant yeast cultures.

Each 0.5 mL dose of COMVAX is formulated to contain 7.5 μg of Haemophilus b PRP, 125 μg of Neisseria meningitidis OMPC, and 5 μg of HBsAg. Each 0.5 mL dose also contains approximately 225 μg of aluminum as aluminum hydroxide, and 35 μg borax as a pH stabiliser, in 0.9% sodium chloride.

The product contains no preservative.

Haemophilus influenzae type b and Neisseria meningitidis serogroup B are grown in complex fermentation media. The PRP is purified from the culture broth by purification procedures which include ethanol fractionation, enzyme digesting, phenol extraction, ultracentrifugation, diafiltration and sterile filtration.

The PRP-OMPC conjugate is prepared by the chemical coupling of the highly purified PRP (polyribosylribitol phosphate) of Haemophilus influenzae type b (Haemophilus b, Ross strain) to an OMPC of the B11 strain of Neisseria meningitidis serogroup B. The coupling of the PRP to the OMPC, is necessary for enhanced immunogenicity of the PRP. This coupling is confirmed by analysis of the components of the conjugate following chemical treatment which yields a unique amino acid. After conjugation, the aqueous bulk is then adsorbed onto an aluminum hydroxide adjuvant.

HBsAg is produced in recombinant yeast cells. A portion of the hepatitis B virus genome, coding for HBsAg, is cloned into yeast, and the vaccine for hepatitis B is produced from cultures of this recombinant yeast strain according to methods developed in the Merck Research Laboratories. The antigen is harvested and purified from fermentation cultures of a recombinant strain of the yeast Saccharomyces cerevisiae containing the gene for the adw subtype of HBsAg. The HBsAg protein is released from the yeast cells by cell disruption and purified by a series of physical and chemical methods. The vaccine contains no detectable DNA, and 1% or less of the protein is of yeast origin. The aqueous bulk is adsorbed onto the aluminum hydroxide adjuvant.

After each PRP-OMPC and HBsAg aqueous bulk is adsorbed onto the aluminum hydroxide adjuvant, they are then combined to produce COMVAX.
The manufacture of this product includes exposure to bovine derived materials. No evidence exists that any case of vCJD (considered to be the human form of bovine spongiform encephalopathy) has resulted from the administration of any vaccine product.

PHARMACOLOGY

Clinical Trials

The immunogenicity of COMVAX (7.5 µg Haemophilus B PRP, 5 µg HBsAg) was assessed in a series of studies involving 3353 infants and children 6 weeks to 15 months of age, 1177 of which received COMVAX. These results were compared with those obtained using component monovalent vaccines, Liquid PedvaxHIB (7.5 µg Haemophilus b PRP) and H-B-VAX II (5 µg HBsAg) given concurrently at separate sites (or one month apart).

In these studies, the immunogenicity of COMVAX was assessed when given as a three-dose series to infants who had or had not, respectively, previously received a dose of hepatitis B vaccine shortly after birth. The antibody responses observed in children given COMVAX under these circumstances are summarised below.

Antibody Responses to COMVAX in Infants Not Previously Vaccinated with Hib or Hepatitis B Vaccine

Table 1 summarises antibody responses of infants in a pivotal multicenter, randomised, open-label study. In this study, 882 infants, approximately 2 months of age, who had not previously received any Hib or hepatitis B vaccine, were assigned to receive a three-dose regimen of either COMVAX or liquid PedvaxHIB plus H-B-VAX II at approximately 2, 4, and 12-15 months of age. The proportions of vaccinees developing clinically important levels of anti-PRP (percent with > 1.0 µg /mL after the second dose) and anti-HBs (percent with ≥ 10 mIU/mL after the third dose) were similar in children given COMVAX or concurrent PedvaxHIB and H-B-VAX II (Table 1).

The anti-PRP response after the second dose among infants given COMVAX in this study (72.4% >1.0 µg /mL; GMT = 2.5 µg /mL) exceeds the response of Native American (Navajo) infants in a previous study of lyophilised PedvaxHIB (60% > 1.0 µg /mL; GMT = 1.43 µg /mL) that was associated with a 93% reduction in the incidence of invasive Hib disease.

In this study, 98.4% of vaccinees developed a protective level of anti-HBs (≥10 mIU/mL) after the third dose of COMVAX. The anti-HBs GMT associated with the use of COMVAX was 4467.5 mIU/mL and the anti-HBs GMT associated with the concomitant use of monovalent PedvaxHIB plus monovalent H-B-VAX II was 6943.9 mIU/mL. Although the difference is statistically significant (p=0.011), both values are much greater than the level of 10 mIU/mL previously established as marking a protective response to hepatitis B. These GMTs are also higher than those observed in three studies conducted by the Merck Research Laboratories in which healthy neonates or young infants received the currently licensed regimen of H-B-VAX II consisting of 2.5 µg doses administered on the standard 0, 1 and 6-month schedule. In those studies, the infants developed GMTs of 257-647 mIU/mL. Two studies have shown that infants given 2.5 µg doses of H-B-VAX II according to the schedule used for COMVAX (2, 4, and 12 - 15 months of age) developed GMTs of 1245-3424 mIU/mL. While a difference in the GMT between two vaccination regimens may result in differential retention of ≥10 mIU/mL of anti-HBs after a number of years, this is of no apparent clinical significance because of immunologic memory.
More than three-quarters of the infants in the study received DTP and OPV concomitantly with the first two doses of COMVAX or PedvaxHIB plus H-B-VAX with just M-M-R II at 15 months of age (Study 2). The third dose of COMVAX was given concomitantly with DTaP (diphtheria, tetanus, acellular pertussis), OPV, and M-M-R II at 14-15 months of age (Study 1) or COMVAX with DTP and OPV reported adverse experiences).

Tolerated in clinical studies (see Table 3 under ADVERSE REACTIONS for a summary of commonly reported adverse experiences).

Clinical studies were done to assess antibody responses to a three dose series of COMVAX in infants who were previously given a birth dose of hepatitis B vaccine. Table 2 summarises the anti-PRP and anti-HBs responses of infants given COMVAX at 2, 4, and 14 to 15 months of age in two clinical studies.

Antibody Responses to COMVAX in Infants Previously Vaccinated with Hepatitis B Vaccine at Birth

Clinical studies were done to assess antibody responses to a three dose series of COMVAX in infants who were previously given a birth dose of hepatitis B vaccine. Table 2 summarises the anti-PRP and anti-HBs responses of infants given COMVAX at 2, 4, and 14 to 15 months of age in two clinical studies.

### Antibody Responses to COMVAX in Infants Previously Vaccinated with Hepatitis B Vaccine at Birth

### Table 2

<table>
<thead>
<tr>
<th>Study</th>
<th>Age (months)</th>
<th>Time</th>
<th>N</th>
<th>Anti-PRP % Subjects with &gt;0.15 μg/mL &gt;1.0 μg/mL</th>
<th>Anti-PRP GMT (μg/mL)</th>
<th>N</th>
<th>Anti-HBs % Subjects ≥10 mIU/mL</th>
<th>Anti-HBs GMT (mIU/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study 1</td>
<td>2</td>
<td>Dose 1*</td>
<td>119</td>
<td>24.4</td>
<td>0.1</td>
<td>71</td>
<td>25.4</td>
<td>2.9</td>
</tr>
<tr>
<td>Study 2</td>
<td></td>
<td>Dose 1**</td>
<td>17</td>
<td>58.8</td>
<td>0.2</td>
<td>15</td>
<td>6.7</td>
<td>0.7</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dose 2**</td>
<td>17</td>
<td>58.8</td>
<td>0.2</td>
<td>15</td>
<td>6.7</td>
<td>0.7</td>
</tr>
</tbody>
</table>

*Postvaccination responses were determined approximately two months after doses 1 and 2.
**Postvaccination responses were determined approximately one month after administration of dose 3.

Infants in these studies received DTP and OPV or eIPV (enhanced inactivated poliovirus vaccine) concomitantly with the first two doses of COMVAX or PedvaxHIB plus H-B-VAX II, and approximately one-third received M-M-R II* (Measles, Mumps and Rubella Virus Vaccine Live) with the third dose of these vaccines at 12 or 15 months of age.

### Concomitant Use of COMVAX with Other Paediatric Vaccines

The concomitant administration of COMVAX with other paediatric vaccines has been generally well tolerated in clinical studies (see Table 3 under ADVERSE REACTIONS for a summary of commonly reported adverse experiences).

**COMVAX with DTP and OPV**

In a series of studies, approximately 200 children receiving COMVAX with a primary series of DTP and OPV developed clinically satisfactory antibody responses to all administered antigens.

**COMVAX with DTaP and eIPV**

Data are currently available from a single study in which infants received COMVAX concomitantly with the primary series of DTaP and eIPV. Following the three-dose primary series of DTaP, 100% of infants had antibodies against diphtheria and tetanus toxins at a level of ≥0.01 antitoxin units/mL (N=18), and 94.4%-100% displayed ≥ fourfold rises in antibodies to the pertussis antigens FHA (N=18) and LPF (N=47) when levels were adjusted for decay in passively acquired maternal antibodies. These results indicate an active response to the diphtheria, tetanus, and acellular
pertussis components of the vaccine. All infants were also seropositive for antibodies to poliovirus types 1, 2, and 3 after two doses of eIPV (N=63).

Two months after the second dose of COMVAX given concomitantly with DTaP and eIPV in this study, 85.7% of infants had >1.0 \mu g/mL of anti-PRP (N=63). This result is higher than that observed in the pivotal trial of COMVAX (see Table 1) and is clinically satisfactory. At the same time, the anti-HBs response was lower than observed previously, with 74.2% of the infants developing ≥10 mIU/mL. In this particular study, infants were given a third dose of COMVAX at 6 months of age. The anti-HBs response one month later on this compressed schedule increased to 92.9% ≥10 mIU/mL (N=56). A separate study on the concomitant administration of COMVAX with DTaP and eIPV according to the licensed schedule of 2, 4, and 15 months of age has not yet been completed. In a previous study, 99% of infants (N=75) given a compressed schedule of monovalent H-B-VAX II at 2, 4, and 6 months developed ≥ 10 mIU/mL of anti-HBs with a GMT of 193 mIU/mL, while in two studies 95-100% of infants (4 groups; aggregate N=148) vaccinated with a more extended schedule of 2, 4, and 12 or 15 months of age developed ≥ 10 mIU/mL of anti-HBs with GMTs ranging from 1245-3424 mIU/mL.

In another study, clinically satisfactory increases in the levels of antibodies to diphtheria toxin, tetanus toxin, and the pertussis antigens LPF and FHA (N=83-84) as well as anti-PRP (N=88) and anti-HBs (N=87) were observed when a booster dose of DTaP was given concomitantly with COMVAX at 14-15 months of age to children previously primed with DTP. The children were also given M-M-R II at this time and most received a dose of OPV as well.

**COMVAX with M-M-R II**
Clinically satisfactory levels of antibodies to measles, mumps, and rubella viruses, anti-PRP, and anti-HBs have been observed in approximately 200 children given COMVAX concomitantly with M-M-R II at 12 to 15 months of age.

**COMVAX with VARIVAX**
Limited data from a single study show that all previously seronegative children seroconverted for antibody to varicella virus and also developed satisfactory anti-PRP and anti-HBs responses when COMVAX was given concomitantly with VARIVAX. Children in the study also received M-M-R II concomitantly at a separate site.

The health-care provider should provide the vaccine information required to be given with each vaccination to the patient, parent or guardian.

The health-care provider should inform the patient, parent or guardian of the benefits and risks associated with vaccination.

**INDICATIONS**

COMVAX is indicated for vaccination against invasive disease caused by *Haemophilus influenzae* type b and against infection caused by all known subtypes of hepatitis B virus in infants 6 weeks to 15 months of age. COMVAX is not suitable for use at birth.

**CONTRAINDICATIONS**

Hypersensitivity to any components of the vaccine.

Individuals who develop symptoms suggestive of hypersensitivity after an injection should not receive further injections of the vaccine.
PRECAUTIONS

COMVAX should not be used in infants younger than 6 weeks of age because this will lead to a reduced anti-PRP response and may lead to immune tolerance (impaired ability to respond to subsequent exposure to the PRP antigen).

Infants born of HBsAg positive mothers should receive Hepatitis B Immune Globulin and Hepatitis B Vaccine (Recombinant) at birth.

If COMVAX is used in persons with malignancies or those receiving immunosuppressive therapy or who are otherwise immunocompromised the expected immune response may not be obtained.

COMVAX will not protect against invasive disease caused by *Haemophilus influenzae* other than type b or against invasive disease (such as meningitidis or sepsis) caused by other microorganisms.

COMVAX will not prevent hepatitis caused by other viruses known to infect the liver. Because of a long incubation period for Hepatitis B, it is possible for unrecognized infection to be present at the time the vaccine is given. The vaccine may not prevent hepatitis B in such patients.

As with other vaccines, COMVAX may not induce protective antibody levels immediately following vaccination and may not result in a protective antibody response in all individuals given the vaccine.

As reported with Haemophilus b Polysaccharide Vaccine and another Haemophilus b Conjugate Vaccine, cases of Haemophilus b disease may occur in the week after vaccination, prior to the onset of the protective effects of the vaccine.

Use caution when vaccinating latex-sensitive individuals since the vial stopper contains dry natural latex rubber that may cause allergic reactions.

As for any vaccine, adequate treatment provisions, including adrenaline, should be available for immediate use should an anaphylactic or anaphylactoid reaction occur.

The decision to administer or delay vaccination because of current or recent febrile illness depends on the severity of symptoms and on the etiology of the disease. It has been recommended that immunization should be delayed during the course of an acute febrile illness. All vaccines can be administered to persons with minor illnesses such as diarrhoea, mild upper-respiratory infection with or without low-grade fever, or other low-grade febrile illness. Persons with moderate or severe febrile illness should be vaccinated as soon as they have recovered from the acute phase of the illness.

**Carcinogenesis, Mutagenesis and Impairment of Fertility**

COMVAX has not been evaluated for its carcinogenic or mutagenic potential, or its potential to impair fertility.

**Use in Pregnancy** (Category B2)

Animal reproduction studies have not been conducted with COMVAX. It is not known whether COMVAX can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity.

COMVAX is not recommended for use in women of childbearing age.

**Use in Lactation**

COMVAX is not indicated for use in persons over the age of 15 months.
Use in Paediatrics

COMVAX has been shown to be generally well tolerated and highly immunogenic in infants 6 weeks to 15 months of age. See DOSAGE AND ADMINISTRATION for recommended dosage schedules.

Safety and effectiveness of COMVAX in infants below the age of 6 weeks and above the age of 15 months have not been established. However, studies have demonstrated that PedvaxHIB is safe and immunogenic when administered to infants and children up to the age of 71 months and H-B-VAX II is safe and immunogenic in persons of all ages.

Use with Other Vaccines

Results from clinical studies indicate that COMVAX can be administered concomitantly with the primary series of DTP and OPV. At 12 to 15 months of age, COMVAX may be given concomitantly with VARIVAX, M-M-R II, or OPV or with a booster dose of DTaP at 15 months of age in children who received the primary series of DTP, using separate sites and syringes for injectable vaccines.

Effects on Laboratory Tests

Sensitive tests (e.g., Latex Agglutination Kits) may detect PRP derived from the vaccine in the urine of some vaccinees for at least 30 days following vaccination with lyophilised PedvaxHIB; in clinical studies with lyophilised PedvaxHIB, such children demonstrated a normal immune response to the vaccine. It is not known whether antigenuria will occur after vaccination with COMVAX.

ADVERSE EFFECTS

In clinical trials involving the administration of 7350 doses of COMVAX to 2993 healthy infants 6 weeks to 15 months of age, COMVAX was generally well tolerated. Of these infants, 1177 were involved in clinical trials in which most received COMVAX concomitantly with other licensed paediatric vaccines. Of these 1177 infants in clinical trials, 1110 were monitored for both serious and non-serious adverse experiences. The remaining 1816 infants were involved in trials where COMVAX was administered concomitantly with either an investigational pneumococcal polysaccharide protein conjugate vaccine or an investigational preparation of diphtheria, tetanus, pertussis, and inactivated poliovirus vaccine and were under surveillance for serious adverse experiences.

Adverse experiences observed within a five-day period following each dose of COMVAX were generally similar in type and frequency to those observed in infants who received concurrent injections of liquid PedvaxHIB and H-B-VAX II at separate sites. As judged by the investigators, no serious vaccine-related adverse experiences were observed during clinical trials.

Table 3 summarises the local reactions and systemic complaints within five days of vaccination that were reported to occur among ≥1.0% of children given a three-dose course of COMVAX as well as the frequencies of these events among children in the study given concomitant injections of monovalent PedvaxHIB and H-B-VAX II. In this randomized, multicenter study, 882 infants were assigned in a 3:1 ratio to receive either COMVAX or PedvaxHIB plus H-B-VAX II at 2, 4, and 12-15 months of age, with the children monitored daily for five days after each injection for local reactions and systemic complaints.

Studies involving 1216 infants (856 given COMVAX) showed that COMVAX was well tolerated; rates of local injection site reactions and systemic adverse experiences in vaccinees given COMVAX were similar to those in vaccinees given separate but concurrent injections of PedvaxHIB and H-B-VAX II. The most frequently cited events were mild, transient signs and symptoms of inflammation at the injection site (i.e. pain/soreness, erythema, and swelling/induration), somnolence, and irritability, all of which were prompted for on report cards filled out by parents of vaccinated children (see Table 3). No child withdrew from these studies because of an adverse experience.
Across the entire clinical program, the frequency of serious adverse experiences within 14 days of vaccination was low, with 33 of 2993 (1.1%) children given COMVAX and 6 of 290 (2.1%) children given concomitant injections of PedvaxHIB and H-B-VAX II having such an event. None of the serious adverse experiences was judged by the study investigator to be related to these vaccines.

### Table 3

<table>
<thead>
<tr>
<th>Event</th>
<th>Injection 1†</th>
<th>Injection 2‡</th>
<th>Injection 3</th>
<th>Injection 4‡</th>
<th>Injection 5‡</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injection Site Reactions</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain/Soreness</td>
<td>34.5</td>
<td>37.6</td>
<td>24.3</td>
<td>25.8</td>
<td>23.9</td>
</tr>
<tr>
<td>Erythema (&gt;1 in.)</td>
<td>22.4 (2.7)</td>
<td>25.6 (2.7)</td>
<td>25.7 (1.4)</td>
<td>23.5 (3.3)</td>
<td>27.2 (3.0)</td>
</tr>
<tr>
<td>Swelling/Induration (&gt;1 in.)</td>
<td>27.6 (3.0)</td>
<td>33.5 (4.1)</td>
<td>30.4 (2.9)</td>
<td>31.0 (3.8)</td>
<td>27.2 (3.2)</td>
</tr>
<tr>
<td>Systemic Complaints</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Irritability</td>
<td>57.0</td>
<td>46.6</td>
<td>50.7</td>
<td>44.1</td>
<td>32.2</td>
</tr>
<tr>
<td>Somnolence</td>
<td>49.5</td>
<td>47.1</td>
<td>37.4</td>
<td>31.9</td>
<td>21.1</td>
</tr>
<tr>
<td>Crying—unusual, high pitched</td>
<td>10.6</td>
<td>8.6</td>
<td>6.7</td>
<td>2.3</td>
<td>2.9</td>
</tr>
<tr>
<td>Anorexia</td>
<td>3.9</td>
<td>2.3</td>
<td>2.0</td>
<td>0.9</td>
<td>0.8</td>
</tr>
<tr>
<td>Vomiting</td>
<td>2.1</td>
<td>1.8</td>
<td>2.5</td>
<td>0.9</td>
<td>1.0</td>
</tr>
<tr>
<td>Otitis media</td>
<td>0.5</td>
<td>0</td>
<td>2.0</td>
<td>1.4</td>
<td>2.7</td>
</tr>
<tr>
<td>Fever (°F, rectal equiv.)†</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>101.0-102.9</td>
<td>14.2</td>
<td>11.9</td>
<td>13.8</td>
<td>12.2</td>
<td>10.5</td>
</tr>
<tr>
<td>≥103.0</td>
<td>0.8</td>
<td>0</td>
<td>1.6</td>
<td>1.4</td>
<td>2.7</td>
</tr>
<tr>
<td>Diarrhoea</td>
<td>1.7</td>
<td>1.8</td>
<td>0.8</td>
<td>0.9</td>
<td>2.2</td>
</tr>
<tr>
<td>Upper respiratory infection</td>
<td>0.5</td>
<td>0.5</td>
<td>1.1</td>
<td>0.9</td>
<td>1.3</td>
</tr>
<tr>
<td>Rash</td>
<td>0.8</td>
<td>0</td>
<td>0.9</td>
<td>0</td>
<td>0.8</td>
</tr>
<tr>
<td>Rhinorhoea</td>
<td>0.2</td>
<td>0</td>
<td>1.1</td>
<td>0.9</td>
<td>1.3</td>
</tr>
<tr>
<td>Respiratory congestion</td>
<td>0.6</td>
<td>0.5</td>
<td>1.2</td>
<td>0.9</td>
<td>0.3</td>
</tr>
<tr>
<td>Cough</td>
<td>0.2</td>
<td>0</td>
<td>0.9</td>
<td>0.5</td>
<td>0.2</td>
</tr>
<tr>
<td>Candidiasis, oral</td>
<td>0.3</td>
<td>0.5</td>
<td>0.8</td>
<td>0</td>
<td>0.2</td>
</tr>
<tr>
<td>Rash, diaper</td>
<td>0.5</td>
<td>0.5</td>
<td>0.5</td>
<td>0.9</td>
<td>0.2</td>
</tr>
</tbody>
</table>

† Overall frequency of each event listed above is ≥1% even though the frequency after a given dose may be <1%.
‡ Most children received DTP and OPV concomitantly with the first two doses of COMVAX or PedvaxHIB and H-B-VAX II.
§ Events prompted for on Vaccination Report Card given to parents/guardians of vaccinees.
The following additional adverse reactions have been reported with use of the marketed vaccine:

**Hypersensitivity:** rarely, anaphylaxis, angioedema, urticaria and erythema multiforme

**Nervous System:** seizure, febrile seizure

**DOSAGE AND ADMINISTRATION**

**FOR INTRAMUSCULAR ADMINISTRATION**

*Do not inject intravenously, intradermally, or subcutaneously.*

Contains no antimicrobial agent. Use once only and discard any residue.

**Recommended Schedule**

Infants should be vaccinated with three 0.5 mL doses of COMVAX, ideally at 2, 4, and 12-15 months of age. If the recommended schedule cannot be followed exactly, the interval between the first two doses should be approximately two months and the interval between the second and third dose should be as close as possible to eight to eleven months.
The Australian Standard Vaccination Schedule recommends that all infants receive a dose of hepatitis B vaccine at birth. Vaccination against Hepatitis B can then be completed with COMVAX administered at 2, 4 and 12-15 months.

Modified Schedules

Children previously vaccinated with one or more doses of either hepatitis B vaccine or Haemophilus b conjugate vaccine
COMVAX may be administered to children scheduled to receive concurrent H-B-VAX II and PedvaxHIB.

Children not vaccinated according to recommended schedule
Vaccination schedules for children not vaccinated according to the recommended schedule should be considered on an individual basis. The number of doses of a PRP-OMPC-containing product (i.e., COMVAX, PedvaxHIB) depends on the age that vaccination is begun. An infant 2 to 10 months of age should receive three doses of a product containing PRP-OMPC. An infant 11 to 14 months of age should receive two doses of a product containing PRP-OMPC. A child 15 to 71 months of age should receive one dose of a product containing PRP-OMPC. Infants and children, regardless of age, should receive three doses of an HBsAg-containing product to help ensure an adequate response to HBsAg.

COMVAX is for intramuscular injection. The anterolateral thigh is the recommended site for intramuscular injection in infants. Data suggests that injections given in the buttocks frequently are given into fatty tissue instead of into muscle. Such injections have resulted in a lower seroconversion rate (for hepatitis B vaccine) than was expected.

COMVAX should not be administered to any infant before the age of 6 weeks.

The vaccine should be used as supplied; no reconstitution necessary.

Shake well before withdrawal and use. Thorough agitation is necessary to maintain suspension of the vaccine.

Parenteral drug products should be inspected visually for extraneous particulate matter and discoloration prior to administration whenever solution and container permit. After thorough agitation, COMVAX is a slightly opaque, white suspension.

OVERDOSAGE

There are no data with regard to overdose. Contact the poisons information center for management of overdose.

PRESENTATION AND STORAGE

COMVAX is a sterile suspension for intramuscular use and is available as a single dose 0.5mL vial. Available in single packs and packs of 10

STORAGE

Store vaccine at 2-8°C.

DO NOT FREEZE since freezing destroys potency.
NAME AND ADDRESS OF THE SPONSOR

MERCK SHARP & DOHME (AUSTRALIA) PTY LIMITED
54-68 Ferndell Street
SOUTH GRANVILLE NSW 2142

DISTRIBUTOR
CSL Biotherapies Pty Ltd
45 Poplar Road, Parkville, VICTORIA 3052

POISON SCHEDULE OF THE MEDICINE

Prescription Only Medicine (Schedule 4)

This document was approved by the Therapeutic Goods Administration on 23 March 2000. Date of most recent amendment 22 December 2010.