

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

PROCOMVAX suspension for injection
Haemophilus b Conjugate (Meningococcal Protein Conjugate) and Hepatitis B (Recombinant) Vaccine

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Polyribosylribitol phosphate (PRP) from *Haemophilus influenzae* type b as PRP-OMPC 7.5 µg

Neisseria meningitidis OMPC (outer membrane protein complex of the B11 strain of *Neisseria meningitidis* subgroup B) 125 µg

Adsorbed hepatitis B surface antigen produced in recombinant yeast cells (*Saccharomyces cerevisiae*) 5.0 µg

in 0.5 ml.

3. PHARMACEUTICAL FORM

Suspension for injection.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

PROCOMVAX 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.

4.2 Posology and method of administration

Method of administration

FOR INTRAMUSCULAR ADMINISTRATION

Do not inject intravenously, intradermally, or subcutaneously.

Posology

Infants born of HBsAg negative mothers should be vaccinated with three 0.5 ml doses of PROCOMVAX, 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. All three doses must be administered to complete the vaccination regimen.

Children who receive one dose of hepatitis B vaccine at or shortly after birth may be administered PROCOMVAX on the schedule of 2, 4, and 12 -15 months of age.

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.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients.

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

Because of the potential for immune tolerance (impaired ability to respond to subsequent exposure to the PRP antigen) PROCOMVAX is not recommended for use in infants younger than 6 weeks of age.

It has been recommended that immunisation should be delayed during the course of an acute febrile illness. All vaccines can be administered to infants with minor illnesses such as diarrhoea or mild upper-respiratory infection. Infants with moderate or severe febrile illness should only be vaccinated as soon as they have recovered from the acute phase of the illness.

4.4 Special warnings and special precautions for use

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

PROCOMVAX must not be mixed with other vaccines in the same syringe.

Infants born of HBsAg-positive mothers should receive Hepatitis B Immune Globulin and Hepatitis B Vaccine (Recombinant) at birth and should complete the hepatitis B vaccination series. The subsequent administration of PROCOMVAX for completion of the hepatitis B vaccination series in infants who were born of HBsAg positive mothers and received HBIG or infants born of mothers of unknown status has not been studied.

In infants with bleeding disorders such as haemophilia or thrombocytopenia, special precautions should be taken against the risk of haematoma following the injection.

Since PROCOMVAX has not been studied in persons who have malignancies or are otherwise immunocompromised, the extent of the immune response in such persons is unknown.

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

PROCOMVAX 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 unrecognised infection to be present at the time the vaccine is given. The vaccine may not prevent hepatitis B in such patients.

PROCOMVAX 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 vaccines.

4.5 Interaction with other medicinal products and other forms of interaction

Use With Other Vaccines

Immunogenicity results from open-labeled studies indicate that PROCOMVAX can be administered concomitantly with DTP (Diphtheria, Tetanus and whole cell Pertussis vaccine), OPV (Oral Poliomyelitis vaccine), IPV (inactivated poliomyelitis vaccine) and Merck MMR

(Measles, Mumps, and Rubella Virus Vaccine Live) using separate sites and syringes for injectable vaccines. Additionally, limited immunogenicity results from an open-labeled, controlled study indicate that PROCOMVAX may be administered concomitantly with DTaP (Diphtheria, Tetanus, and acellular Pertussis vaccine), using separate sites and syringes for injectable vaccines.

Efficacy of whole cell or acellular pertussis vaccines when given concomitantly with PROCOMVAX has not been established in field trials.

4.6 Pregnancy and lactation

Not applicable. For paediatric use only.

4.7 Effects on ability to drive and use machines

Not applicable. For paediatric use only.

4.8 Undesirable effects

In clinical trials involving the administration of 7,350 doses of PROCOMVAX to 2,993 healthy infants 6 weeks to 15 months of age, PROCOMVAX was generally well tolerated. Of these infants, 1,177 were involved in clinical trials in which most received PROCOMVAX concomitantly with other licensed paediatric vaccines. Of these, 1,110 were monitored for both serious and non-serious adverse experiences. The remaining 1,816 infants were involved in trials where PROCOMVAX 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.

Among the 2,993 children given PROCOMVAX, 33 had serious adverse experiences within 14 days of vaccination. None of the serious adverse experiences was judged by the study investigator to be related to this vaccine.

In one of these trials, a randomized, multicenter study, 882 infants were assigned in a 3:1 ratio to receive either PROCOMVAX or Merck Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate) (Merck PRP-OMPC Vaccine) plus Merck Hepatitis B (Recombinant) Vaccine 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. Most children received DTP and OPV concomitantly with the first two doses of PROCOMVAX or Merck PRP-OMPC Vaccine or Merck Hepatitis B (Recombinant) Vaccine. Across all three doses of PROCOMVAX, there were no significant differences in the frequency of adverse experiences between PROCOMVAX and the monovalent vaccines Merck PRP-OMPC Vaccine and Merck Hepatitis B (Recombinant) Vaccine. However, the frequency of irritability was statistically higher after all three injections of PROCOMVAX combined and after the first injection of PROCOMVAX compared to the monovalent vaccines. Also, the frequency of unusual high-pitched crying was statistically higher after the second injection of PROCOMVAX than after the second injection of the monovalents.

The following local reactions and systemic complaints were reported in **Error! No bookmark name given.** 1.0 % of children within five days after any injection of PROCOMVAX: pain/soreness, erythema, swelling/induration at the injection site; fever (> 38.3 °C, rectal equivalent); anorexia, vomiting, diarrhoea; irritability, somnolence, crying including unusual high-pitched crying, prolonged crying (> 4 hrs), and crying not otherwise specified; otitis

media. No increase in the frequency or severity of adverse events was seen with subsequent doses.

Potential Adverse Effects

In addition, a variety of adverse effects have been reported with marketed use of either Merck PRP-OMPC Vaccine or Merck Hepatitis B (Recombinant) Vaccine in infants and children through 71 months of age. These adverse effects are listed below.

Liquid Merck PRP-OMPC Vaccine

Hypersensitivity
Rarely, angioedema

Haematologic/Lymphatic

Lymphadenopathy

Nervous System

Febrile seizures

Skin

Sterile injection-site abscess; pain at the injection site

Merck Hepatitis B (Recombinant) Vaccine

Common reactions

Local reactions at injection site: transient soreness, erythema, induration

Rare

- elevation of liver enzymes, fatigue, fever, malaise, influenza-like symptoms, bronchospasm-like symptoms, serum sickness, thrombocytopenia
- dizziness, headache, paresthesia
- nausea, vomiting, diarrhea, abdominal pain
- arthralgia, myalgia
- rash, pruritus, urticaria, anaphylaxis
- hypotension, syncope
- paralysis (Bell's palsy), neuropathy, neuritis (including Guillain Barre Syndrome, myelitis including transverse myelitis), encephalitis, optical neuritis.
- angioedema, erythema multiforme
- lymphadenopathy.

4.9 Overdose

There are no data with regard to overdose.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group : anti infectious, ATC code : J07CA

5.1 Pharmacodynamic properties

PROCOMVAX is a sterile bivalent vaccine made of the antigenic components used in producing Merck PRP-OMPC Vaccine and Merck Hepatitis B (Recombinant) Vaccine. 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.

The protective efficacy of the components of PROCOMVAX has been established in field trials performed with the monovalent vaccines.

Clinical Studies - Immunogenicity of PROCOMVAX

The immunogenicity of PROCOMVAX (7.5 µg Haemophilus b PRP, 5.0 µg HBsAg) was assessed in a series of studies involving 3,353 infants and children 6 weeks to 15 months of age.

In these studies, the immunogenicity of PROCOMVAX 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. PROCOMVAX was also used to complete the Hib or hepatitis B vaccination series in children previously given a primary course of another Hib vaccine (2 or 3 doses depending on type) and 2 or 3 doses of a hepatitis B vaccine. The antibody responses observed in children given PROCOMVAX under these circumstances are summarised below.

Antibody Responses to PROCOMVAX 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 PROCOMVAX or liquid Merck PRP-OMPC Vaccine plus Merck Hepatitis B (Recombinant) Vaccine at approximately 2, 4, and 12-15 months of age. The proportions of vaccinees developing clinically important levels of anti-PRP (percent with > 0.15 µg/ml and > 1.0 µg/ml after the second dose) and anti-HBs (percent with **Error! No bookmark name given.** 10 IU/ml after the third dose) were similar in children given PROCOMVAX or concurrent Merck PRP-OMPC Vaccine and Merck Hepatitis B (Recombinant) Vaccine (Table 1).

In this study, 98.4 % of vaccinees developed a protective level of anti-HBs (**Error! No bookmark name given.** 10 mIU/ml) after the third dose of PROCOMVAX. The anti-HBs GMT associated with the use of PROCOMVAX was 4,467.5 mIU/ml and the anti-HBs GMT associated with the concomitant use of monovalent Merck PRP-OMPC Vaccine plus monovalent Merck Hepatitis B (Recombinant) Vaccine was 6,943.9 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. While a difference in the GMT between two vaccination regimens may result in differential retention of **Error! No bookmark name given.** 10 mIU/ml of anti-HBs after a number of years, this is of no apparent clinical significance because of immunologic memory.

Table 1

Antibody Responses to PROCOMVAX, liquid Merck PRP-OMPC Vaccine, and Merck Hepatitis B (Recombinant) Vaccine in Infants Not Previously Vaccinated with Hib or Hepatitis B Vaccine

Vaccine	Age (months)	Time	N	Anti-PRP % Subjects with > 0.15 µg/ml	Anti-PRP % Subjects with > 1.0 µg/ml	Anti-PRP GMT (µg/ml)	N	Anti-HBs % Subjects	Anti-HBs GMT mIU/ml
PROCOMVAX (7.5 µg PRP, 5.0 µg HBsAg)	2	Prevaccination	633	34.4	4.7	0.1	603	10.6	0.6
	4	Post Dose 1	620	88.9	51.5	1.0	595	34.3	4.2
	6	Post Dose 2	576	94.8	72.4	2.5	571	92.1	113.9
	12/15	Pre Dose 3	588	77.0	22.1	0.4	585	79.0	32.3
	13/16	Post Dose 3	570	99.3	92.6	9.5	571	98.4	4,467.5
Liquid Merck PRP-OMPC Vaccine (7.5 µg PRP) + Merck Hepatitis B (Recombinant) Vaccine (5.0 µg HBsAg)	2	Prevaccination	208	33.7	5.8	0.1	196	7.1	0.5
	4	Post Dose 1	202	90.1	53.5	1.1	198	41.9	5.3
	6	Post Dose 2	186	95.2	76.3	2.8	185	98.4	255.7
	12/15	Pre Dose 3	187	80.2	28.9	0.5	186	96.2	197.5
	13/16	Post Dose 3	181	98.9	92.3	10.2	179	100	6,943.9

More than three-quarters of the infants in the study received DTP and OPV concomitantly with the first two doses of PROCOMVAX or Merck PRP-OMPC Vaccine plus Merck Hepatitis B (Recombinant) Vaccine, and approximately one-third received MMR with the third dose of these vaccines at 12 or 15 months of age.

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

Clinical studies were done to assess antibody responses to a three dose series of PROCOMVAX 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 PROCOMVAX at 2, 4, and 14 to 15 months of age in two clinical studies.

Table 2

Antibody Responses to PROCOMVAX in Infants Previously vaccinated with Hepatitis B Vaccine at Birth

Study	Age (months)	Time	N	Anti-PRP % Subjects with > 0.15 µg/ml	Anti-PRP % Subjects with > 1.0 µg/ml	Anti-PRP GMT (µg/ml)	N	Anti-HBs % Subjects	Anti-HBs GMT mIU/ml
Study 1	2	Prevaccination	119	24.4	5.9	0.1	71	25.4	2.9
	4	Post Dose 1	-----	----- Not	----- Measured ----	-----	-----	-----	-----
	6	Post Dose 2	111	94.6	81.1	3.3	111	98.2	417.2
	14/15	Pre Dose 3	101	71.3	21.8	0.4	101	90.1	55.7
	15/16	Post Dose 3	88	100	93.2	11.0	87	98.9	3,500.7
Study 2	2	Prevaccination	17	58.8	0	0.2	15	6.7	0.7
	4	Post Dose 1	17	88.2	47.1	0.9	16	81.3	35.2
	6	Post Dose 2	17	100	76.5	2.8	16	100	281.8
	15	Pre Dose 3	17	88.2	23.5	0.4	17	88.2	64.1
	17	Post Dose 3	15	100	100	8.5	16	100	3,913.4

Infants in these studies received DTP and OPV or IPV concomitantly with the first two doses of PROCOMVAX, while the third dose of PROCOMVAX was given concomitantly with DTaP, OPV and MMR at 14-15 months of age (Study 1) or with just MMR at 15 months of age (Study 2).

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Formulation contains aluminium hydroxide and sodium borate in 0.9 % sodium chloride.

6.2 Incompatibilities

Do not mix with other vaccines or other medicinal products in the same syringe.

6.3 Shelf life

24 months

The expiry date is indicated on the label and packaging.

6.4 Special precautions for storage

Store at +2 °C to +8 °C (in a refrigerator).

Do not freeze.

6.5 Nature and contents of container

0.5 ml suspension in vial (type 1 flint glass).

6.6 Instructions for use and handling

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

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

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

7. MARKETING AUTHORISATION HOLDER

Pasteur Mérieux MSD
8, rue Jonas Salk
F - 69007 LYON
France

8. NUMBER(S) IN THE COMMUNITY REGISTER OF MEDICINAL PRODUCTS

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT

ANNEX II

- A. MANUFACTURING AUTHORISATION HOLDER
RESPONSIBLE FOR BATCH RELEASE AND
MANUFACTURER OF THE BIOLOGICAL ACTIVE
SUBSTANCES**

- B. CONDITIONS OF THE MARKETING
AUTHORISATION**

A. MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE AND MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCES

Name and address of the manufacturer of the biological active substances

For Haemophilus B conjugate and Hepatitis B surface antigen:

Merck & Co. Inc.
Sumneytown Pike
West Point
Pennsylvania 19486 USA

A favourable inspection report was issued on 17 November 1998, by the Ministry of Health, Welfare and Sport, Inspectorate of Health Care, P. O. Box 5850, 2280 HW Rijswijk, Netherlands.

Name and address of the manufacturer responsible for batch release

Merck Sharp & Dohme B. V.
Waarderweg 39,
2003 PC Haarlem
Netherlands

Manufacturing authorisation issued on 27 January 1998, by the Ministry of Health, Welfare and Sport, Inspectorate of Health Care, P. O. Box 5850, 2280 HW Rijswijk, Netherlands.

B. CONDITIONS OF THE MARKETING AUTHORISATION

• **CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IMPOSED ON THE MARKETING AUTHORISATION HOLDER**

Medicinal product subject to medical prescription.

• **OTHER CONDITIONS**

Official batch release: in accordance with Article 4 of Council Directive 89/342/EEC, the official batch release will be undertaken by a state laboratory or a laboratory designated for that purpose.

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

CARTON - SINGLE DOSE VIAL

PROCOMVAX suspension for injection
Haemophilus b Conjugate (Meningococcal Protein Conjugate) and Hepatitis B (recombinant)
Vaccine

1 single dose vial = 0.5 ml

For intramuscular use

1 dose (0.5 ml) contains :

7.5 µg of PRP from *Haemophilus influenzae* type b as PRP-OMPC

125 µg of *Neisseria meningitidis* OMPC

5.0 µg of hepatitis B surface antigen produced in recombinant yeast cells

Aluminium hydroxide and sodium borate in 0.9 % sodium chloride

Store at +2 °C - +8 °C (in a refrigerator).

Do not freeze

Shake well before use

Keep out of the reach and sight of children

Medicinal product subject to medical prescription

EU/././.../...

Marketing Authorisation Holder :

Pasteur Mérieux MSD

8, rue Jonas Salk

F - 69007 LYON

France

Batch :

EXP. :

SINGLE DOSE VIAL LABEL

PROCOMVAX

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

1 dose = 0.5 ml

Suspension for intramuscular injection

Store at + 2 °C - + 8 °C (in a refrigerator)

Do not freeze

Shake well before use

PASTEUR MERIEUX MSD

Batch :

EXP :

Batch :

EXP :

PROCOMVAX

PASTEUR MERIEUX MSD

Batch :

EXP :

PROCOMVAX

PASTEUR MERIEUX MSD

B. PACKAGE LEAFLET

PROCOMVAX suspension for injection
Haemophilus b Conjugate (Meningococcal Protein Conjugate) and Hepatitis B (Recombinant) Vaccine

What is PROCOMVAX?

PROCOMVAX [Haemophilus b Conjugate (Meningococcal Protein Conjugate) and Hepatitis B (Recombinant) Vaccine] is indicated for vaccination against invasive disease (infection of brain and spinal cord tissues, infection of the blood, etc.) caused by *Haemophilus influenzae* type b (Hib) bacterium and against infection of the liver caused by all known subtypes of hepatitis B virus (HBV) in infants 6 weeks to 15 months of age born of HBsAg negative mothers. Each 0.5 ml dose of injectable vaccine contains 7.5 µg of Haemophilus b polyribosylribitolphosphate (PRP) conjugated to 125 µg of OMPC (Outer Membrane Protein Complex of *Neisseria Meningitidis*) and 5.0 µg of HBsAg produced in recombinant yeast cells as active substances.

In addition, PROCOMVAX contains the following ingredients: aluminium hydroxide, sodium borate in 0.9 % sodium chloride.

PROCOMVAX is available as a 0.5 ml single dose vial.

Marketing Authorisation Holder : **Manufacturer responsible for batch release :**

Pasteur Mérieux MSD
8 rue Jonas Salk
F-69007 Lyon
France

Merck Sharp & Dohme B.V.
Waarderweg 39,
P.O. Box 581
NL-2003 PC Haarlem
The Netherlands

Why has my doctor recommended/administered PROCOMVAX?

Your doctor has recommended/administered PROCOMVAX to help protect your child against invasive disease caused by *Haemophilus influenzae* type b (infection of brain and spinal cord tissues, infection of the blood, etc.) and against infection of the liver caused by all known subtypes of hepatitis B virus. The vaccine can be administered in most infants 6 weeks to 15 months of age.

What should I know before vaccination with PROCOMVAX?

Who should not be vaccinated with PROCOMVAX?

Anyone who is allergic to any component of the vaccine.
Infants younger than 6 weeks of age.
Vaccination should be delayed in children with fever.
Infants born to HBsAg positive mothers.

What should I tell my doctor before my child is vaccinated with PROCOMVAX?

Tell your doctor about any present or past medical problems or allergies, including allergic reactions after any dose of PROCOMVAX .

Use in children

PROCOMVAX can be used in infants 6 weeks to 15 months of age.

Can my child be vaccinated with PROCOMVAX and other vaccines simultaneously ?

PROCOMVAX can be administered simultaneously with the primary series of diphtheria, tetanus, pertussis vaccine (DTP) and oral polio vaccine (OPV). At 12 to 15 months of age, PROCOMVAX may be given simultaneously with Merck MMR (Measles, Mumps, and Rubella Virus Vaccine Live), or OPV or with a booster dose of diphtheria, tetanus, acellular pertussis vaccine (DTaP) at 15 months of age in children who received the primary series of DTP.

PROCOMVAX has been administered simultaneously with the primary series of DTaP and enhanced inactivated poliovirus vaccine (IPV) to a limited number of infants. No serious vaccine-related side effects were reported. Immune response data are satisfactory for PROCOMVAX but are currently unavailable for DTaP.

See your doctor for more information.

Other Considerations

As with other similar vaccines, cases of *Haemophilus b* disease may occur in the week after vaccination prior to the onset of the protective effects of the vaccine.

Because hepatitis B infection can go undetected for a long period of time, it is possible that an individual may already be infected at the time the vaccine is given. The vaccine may not prevent hepatitis B in these individuals.

What is the vaccination schedule for PROCOMVAX ?

Infants should be vaccinated with three 0.5 ml doses of PROCOMVAX.

Infants born of HBsAg negative mothers should be vaccinated with three 0.5 ml doses of PROCOMVAX, 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. All three doses must be administered to complete the vaccination regimen.

How should PROCOMVAX be given ?

PROCOMVAX must be injected into the muscle of the thigh.

What should I do if my child misses a dose ?

Your doctor will decide when to give the missed dose.

What side effects may PROCOMVAX have ?

Any vaccine may have some side effects. PROCOMVAX has been generally well tolerated in clinical trials. Side effects include injection-site reactions such as pain, soreness, redness, and swelling. Other side effects include irritability, sleepiness, fever, diarrhoea, vomiting, loss of appetite, middle ear infection, and unusual high-pitched crying.

Tell your doctor promptly about these or any other unusual symptoms. If the condition persists or worsens, seek medical attention.

In addition, tell your doctor if your child experienced any symptoms that suggest an allergic reaction after any dose in the vaccination series.

How can I learn more about PROCOMVAX ?

Not all the information about this vaccine is printed here. If you have any questions ask your doctor who has the full prescribing information.

How should I store PROCOMVAX ?

Store PROCOMVAX in the refrigerator at +2 °C - +8 °C.

DO NOT FREEZE PROCOMVAX.

Do not use PROCOMVAX after the date printed on the label.

Keep out of the reach and sight of children.

When was this package leaflet last revised ?

This package leaflet was last revised on _____.

12. OTHER INFORMATION

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

België/Belgique/Belgien

PASTEUR MERIEUX MSD
Avenue Jules Bordet, 13
B-1140 BRUXELLES/BRUSSEL
Tel: 32.2.726.95.84

Luxembourg/Luxemburg

PASTEUR MERIEUX MSD
Avenue Jules Bordet, 13
B-1140 BRUXELLES
Belgique/Belgien
Tel: 32.2.726.95.84

Danmark

PASTEUR MERIEUX MSD
Toldbodgade 57
DK-1253 KØBENHAVN K
Tel: 45.33.33.71.11

Nederland

PASTEUR MERIEUX MSD
Avenue Jules Bordet, 13
B-1140 BRUSSEL
België
Tel: 32.2.726.95.84

Deutschland

Chiron Behring GmbH & Co
Postfach 16 30
D-35006 MARBURG
Tel: 49.180.5.25.16.16

Österreich

PASTEUR MERIEUX CONNAUGHT
AUSTRIA Ges.m.b.H
Richard Strauss Strasse 33
A-1230 WIEN
Tel: 43.1.610.47

Ελλάδα

PASTEUR MERIEUX MSD
Via Di Villa Troili 56
I-00163 Ρώμη
Ιταλία
Tel: 39.0.6.664.092.11

Portugal

UCB PHARMA Lda
Rua Gregorio Lopes - Lote 1597 - 1º
P-1400 LISBOA
Tel: 35.1.1.302.53.00

España

PASTEUR MERIEUX MSD
Calle Joseta Valcarcel, 40, 3º
E-28027 MADRID
Tel: 34.9.1.371.78.00

Suomi/Finland

PASTEUR MERIEUX MSD
Toldbodgade 57
DK-1253 KØBENHAVN K
Tanska
Tel: 45.33.33.71.11

France

PASTEUR MERIEUX MSD
8, rue Jonas Salk
F-69007 LYON
Tel: 33.4.37.28.40.00

Sverige

PASTEUR MERIEUX MSD
Toldbodgade 57
DK-1253 KØBENHAVN K
Danmark
Tel: 45.33.33.71.11

Ireland

PASTEUR MERIEUX MSD
Belgard Road
Tallaght
IRL-DUBLIN 24

United Kingdom

PASTEUR MERIEUX MSD
Mallards Reach
Bridge Avenue
MAIDENHEAD

Tel: 35.31.295.2226

BERKSHIRE SL6 1QP-UK

Tel: 44.1.628.785.291

Italia

PASTEUR MERIEUX MSD

Via Di Villa Troili 56

I-00163 ROMA

Tel: 39.06.664.092.11