

COMVAX[®]

haemophilus influenzae type b (Hib) conjugate and hepatitis B vaccine

0.5 mL Vial

What is in this leaflet

This leaflet answers some common questions about COMVAX. It does not contain all the available information. It does not take the place of talking to your doctor.

All medicines and vaccines have risks and benefits. Your doctor has weighed the risks of your child being given COMVAX against the benefits they expect it will have for your child.

If you have any concerns about your child being given this vaccine, ask your doctor.

Keep this leaflet with the medicine. You may need to read it again.

What COMVAX is used for

COMVAX is a vaccine used to help prevent hepatitis B and Haemophilus influenzae type b disease. It can be given to infants between 6 weeks to 15 months of age.

Hib disease

Haemophilus b disease is an infection caused by a germ called Haemophilus influenzae type b (H. influenzae type b or HIB for short). Protection against Hib is important because this germ, or bacterium, can cause serious disease, such as meningitis, which is an infection of the brain or spinal cord tissues. It can also cause infection of the blood or joints.

Infection from Hib bacteria usually occurs when an infant comes into contact with an infected person. The infection may be spread when an infected person coughs or sneezes near another child. Situations that may increase your child's risk of infection include:

- being around groups of other children (e.g. Daycare)
- living in the same household as someone who is infected
- having certain medical conditions, including sickle disease, some immune disorders and having had the spleen removed.

Children who get Haemophilus b disease of the brain or spinal cord tissues (meningitis) often develop a cold or sore throat first. This is followed by fever, headache, stiff neck, vomiting, high pitched crying, and/or convulsions.

Most children recover completely from Haemophilus b disease. However, about 35% of those children who recover from the infection end up with permanent brain damage including seizures, deafness and mental retardation.

Prior to the vaccine being introduced in New Zealand in 1994, Hib was the most common illness caused by bacteria to threaten the life of New Zealand children under 5 years of age with one in every 350 children under five becoming seriously ill. Hib disease has nearly disappeared since immunisation started.

Vaccination is the best way to protect against this disease. COMVAX helps protect against Hib infection, not against other germs that cause meningitis.

Hepatitis B

Hepatitis B is an infection of the liver caused by the hepatitis B virus (HBV). It can be caught by coming into contact with an infected person's blood, semen, vaginal secretions, saliva or other body fluids. For example, if these infectious fluids enter your blood stream through a cut in your skin, you could become infected. Other situations that could lead to infection include being born to a mother who carries the HBV, living in the same house as someone who is infected, and travelling to areas where hepatitis B is common.

People who have hepatitis B may not look or feel sick when infected. In fact, a person could be infected by the virus six weeks to six months before symptoms occur. Some people develop mild, flu-like symptoms. Others may become very ill and extremely tired, develop yellowing of the skin and/or eyes (also called jaundice), dark urine and other symptoms that require hospitalisation.

Most people recover completely from the HBV infection. However, there are some people, particularly children, who may not have symptoms but continue to carry the virus in their blood. They are called chronic carriers. These chronic carriers are infectious and can spread the disease to others throughout their lives.

Babies who are infected with the HBV at birth, almost always go on to become chronic carriers. The infection at birth is silent, and the babies appear healthy and continue to remain healthy for many years. However, after 30, 40 or 50 years they can become unwell and develop the symptoms described above.

All chronic carriers run the risk of developing serious liver disease, such as cirrhosis (scarring of the liver) or liver cancer.

There is no specific treatment for hepatitis B. Therefore, vaccination is the best way to help protect against infection and possible serious long-term disease.

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.

Vaccination is the best way to protect against this disease. COMVAX will not protect against hepatitis caused by other agents or viruses (such as hepatitis A, hepatitis C, hepatitis D, hepatitis E).

How COMVAX works

The vaccine contains a fragment (small section) of the bacteria and is injected into the body. The body then produces its own protection by making disease-fighting substances (antibodies) to fight the bacteria. The vaccine itself cannot cause the infection. If a vaccinated child comes into contact with the live bacteria the body is usually ready, and produces antibodies to destroy them.

Your child needs to have a course of injections before full protection can develop against Hib disease and hepatitis B. However, as with all vaccines, even after the course, 100% protection cannot be guaranteed.

The chance of a severe reaction from COMVAX is very small, but the risks from not being vaccinated may be very serious.

Before your child is given COMVAX

COMVAX should not be given if

- your child has an allergy to COMVAX or any of the ingredients listed at the end of this leaflet.

If you are not sure whether your child should be given COMVAX, talk to your doctor. COMVAX should not be given to infants under 6 weeks of age.

Before your child is given COMVAX

Tell your doctor if your child:

- has any medical conditions, especially diseases which decrease the immune system, for example, AIDS or cancer.
COMVAX may not work as well as it should if your child has diseases or conditions which decrease the body's immune defence system. Your doctor will decide whether or not to give the vaccine.
- has an infection or a high temperature
Your doctor may decide to delay the injection of COMVAX. If this happens please get your child immunised as soon as he/she is better.
- has any allergies to any other medicines or any other substances, such as foods, preservatives, latex rubber or dyes.

If you have not told your doctor about any of the above, tell them before your child is given COMVAX.

Taking other medicines

Tell your doctor if your child is taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

COMVAX may not work as well as it should if your child is taking medicines that decrease the immune system, such as corticosteroids (e.g. prednisone) or cyclosporin. Your doctor will advise you if your child is taking any of these or other medicines that decrease the immune system. Your doctor will decide whether or not to give the vaccine.

Use with other vaccines

COMVAX may be given at the same time as the series of diphtheria, tetanus and whooping cough (pertussis) vaccine, and oral polio vaccine.

If COMVAX is given at the same time as other vaccine injections, the injections should be given at different places on the body and using separate syringes. Your doctor will decide if COMVAX should be given with other vaccines.

How COMVAX is given

How much is given

The usual dose of COMVAX for infants 6 weeks to 15 months of age is 0.5 mL.

How it is given

COMVAX is given as an injection, by the nurse or doctor, usually into the upper thigh muscle.

The vaccine should not be injected directly into veins (intravenously) or under the skin (subcutaneously).

Vaccination schedule

Infants should be vaccinated with 0.5 mL doses of COMVAX, ideally at 2, 4, and 12-15 months of age.

The New Zealand Vaccination Schedule recommends that infants receive COMVAX at 6 weeks and 3 months of age followed by a single dose of monovalent Hepatitis B (Hep B) at 5 months and Haemophilus influenza type b (Hib) at 1 month of age.

Note: the schedule for COMVAX in New Zealand is different from other parts of the world and is decided by a local panel of experts. Therefore, the information in this sheet may be somewhat different to the information supplied with the vaccine or on some internet sites. It may take up to one week after vaccination for protection to develop against Hib disease, so there is a very small risk that Hib infections may occur during this time.

Keep a record of your child's vaccinations and update this after each injection.

Keep your child's follow-up appointment with your doctor or clinic.

It is important for your child to have the follow-up doses of COMVAX at the appropriate times to make sure the vaccine has the best chance of providing protection against hepatitis B and Hib disease.

If a dose is missed

If your child misses a scheduled dose, talk to your doctor and arrange another visit as soon as possible.

Adverse Effects

Tell your doctor as soon as possible if your child does not feel or look well during or after having had an injection of COMVAX.

COMVAX helps protect most infants from hepatitis B and Hib disease, but it may have unwanted side effects in a few people. All medicines and vaccines can have side effects. Sometimes they are serious; most of the time they are not. Your child may need medical treatment if they get some of the side effects.

Ask your doctor to answer any questions you may have.

Mild effects

Tell your doctor if your child has any of the following and they are troublesome or ongoing:

- rash
- local reaction around the injection site such as pain, soreness, redness, swelling or a hard lump
- irritability
- unusual, high-pitched crying or crying more than normal
- sleepiness
- fever
- smaller appetite than normal
- cold or flu-like symptoms such as sneezing, runny or blocked nose, cough, red or infected throat
- ear infection
- vomiting, diarrhoea
- thrush in the mouth, which appears as creamy-yellow, raised patches

These are the more common side effects. For the most part these have been mild.

More serious effects that may rarely occur

Tell your doctor immediately or go to accident and emergency at your nearest hospital if you notice your child has any of the following:

- skin rash, hives or other symptoms that suggest an allergic reaction
- swelling of the face, lips, mouth, throat or tongue which may cause difficulty in swallowing or breathing.
- seizures (including those associated with a fever)

These may be signs of a serious allergic reaction. Your child may need urgent medical attention. Serious side effects are rare.

Other side effects not listed above may also occur in some infants. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects. Your child may not experience any of them.

Storage

COMVAX should be stored between 2-8°C. DO NOT FREEZE.

Product description

What it looks like

COMVAX comes in vials. After shaking, it appears as a slightly opaque, white suspension. Each vial contains a single dose.

Ingredients

Active ingredients:

There are 2 active ingredients:

A fragment (small section) of Haemophilus influenzae type b bacteria, linked to a protein. The scientific name is Haemophilus influenzae type b polysaccharide - conjugated to Neisseria meningitidis outer membrane protein complex.

Surface protein of the hepatitis B virus, derived from genetically engineered yeast cells. This is not infectious, and will not give you the hepatitis B virus.

Inactive ingredients:

- amorphous aluminium hydroxyl phosphate
- sodium borate
- sodium chloride

COMVAX is made without any human blood or blood products, or any other substances of human origin. It does not contain any infectious material.

Further information

Not all the information about this vaccine is printed here. If you have any questions ask your doctor who has the full prescribing information. You can also ring the Immunisation Advisory Centre (IMAC) on freephone 0800 IMMUNE (0800 466 863).

Manufacturer

Merck & Co Inc
Sumneytown Pike, West Point, PA 19486, USA

Supplier

COMVAX is supplied in New Zealand by:

Merck Sharp & Dohme (New Zealand) Limited
P O Box 99 851
Newmarket
Auckland
NEW ZEALAND
Tel: 0800 500 673

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COMVAX is a prescription only medicine.

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