

VACCINATION CONSENT FORM

ENGERIX-B 10 micrograms/0.5 mL Suspension for injection in prefilled syringe Recombinant hepatitis B vaccine, adsorbed

Please answer the following questions:

(⊗ Mark with a cross where applicable)

Speak to your vaccinator if you have any further questions about this vaccination.

Please bring any existing vaccination documentation (vaccination card or certificate) with you to your scheduled immunization appointment.

	Yes	No
Is your child suffering from an acute illness or has he/she had an acute illness within the past 7 days (e.g. fever, cough, runny nose, sore throat, or other)? If yes, which illness?	<input type="checkbox"/>	<input type="checkbox"/>
Does your child have an allergy (especially to egg white, medicines)? If yes, to what?.....	<input type="checkbox"/>	<input type="checkbox"/>
Does your child take any medication regularly (e.g. cortisone, cytostatics or blood thinning agents)? If yes, which one(s)?	<input type="checkbox"/>	<input type="checkbox"/>
Is your child suffering from any severe or chronic illness ? (e.g. an inherited or acquired immunodeficiency disease, cancer, autoimmune disease, blood clotting disorder, chronic inflammation of the brain or spinal cord, epileptic seizures) If yes, which illness?.....	<input type="checkbox"/>	<input type="checkbox"/>
Has your child had problems or side effects after being vaccinated in the past (except for slight local reactions such as reddening, swelling, pain at the injection site or mild fever)?	<input type="checkbox"/>	<input type="checkbox"/>
Has your child received any other vaccination within the last 4 weeks ? If yes, which one..... and when?	<input type="checkbox"/>	<input type="checkbox"/>
Has your child had a blood transfusion , an injection of immunoglobulin , or received any blood products in the last 3 months ?	<input type="checkbox"/>	<input type="checkbox"/>
Is your child currently undergoing chemotherapy and/or radiotherapy ?	<input type="checkbox"/>	<input type="checkbox"/>
Has your child undergone any invasive procedure recently (e.g. a surgery)?	<input type="checkbox"/>	<input type="checkbox"/>
If the adolescent to be vaccinated should be pregnant , please indicate with a cross!	<input type="checkbox"/>	<input type="checkbox"/>

Please turn over - thank you!

Please fill out in block capitals - thank you

----- Child's last name	----- Child's first name
----- Address	
----- Child's health insurance number	----- Child's birth date: Day/Month/Year
----- Name of health insurance provider (e.g. WGKK)	
----- Name of legal guardian	

I confirm with my signature, that I have read and understood the package leaflet for the above mentioned vaccine. I have taken account of the information given there on vaccine composition, any contraindications against its administration and possible side effects. The benefits and risks of vaccination were explained to me in sufficient detail and I had the opportunity to clarify any unanswered questions with the vaccinator.

I agree to be vaccinated.

I agree to the transfer of data for invoicing purposes and electronic documentation in a computer program.

Date

Signature of the person being vaccinated or of parent/legal guardian

Underage children (children under the age of 14) require the consent of one parent or the person responsible for the child's upbringing (legal guardian). Adolescents must give their consent themselves provided that they possess reasoning ability and power of judgement.

Information:

- This vaccination is recommended by the Federal Ministry of Health and is provided free of charge within the Austrian vaccination scheme.
- For further information please refer to the vaccination brochure or visit the website of the Federal Ministry of Health at www.bmg.gv.at under "Vaccinations".
- If any side effects occur, please inform your vaccine provider.
- **If you miss a vaccination appointment, please make sure you are given the missed vaccination as soon as possible.**

Doctor's comments:

Date

Doctor's stamp and signature

IMPORTANT NOTES ON THE VACCINE

ENGERIX-B 10 micrograms/0.5 mL

Suspension for injection in prefilled syringe

Recombinant hepatitis B vaccine, adsorbed

WHAT ENGERIX-B IS AND WHAT IT IS USED FOR

ENGERIX-B is a vaccine against hepatitis B. The vaccine works by stimulating the production of antibodies against this disease.

Hepatitis B is an inflammation of the liver caused by the hepatitis B virus. The virus is found in body fluids of infected persons, including blood, semen, vaginal secretions or saliva.

Vaccination is the best protection against this disease. None of the ingredients in the vaccine are infectious.

BEFORE ENGERIX-B IS GIVEN TO YOU OR YOUR CHILD

ENGERIX-B should not be given if

- you/your child have/has ever had an allergic reaction to ENGERIX-B or any of the excipients contained in this vaccine. The active substance and excipients in ENGERIX-B are listed in section 6 "Further information". An allergic reaction may include an itchy skin rash, difficulty in breathing or swelling of the face or tongue.
- you/your child have/has ever had an allergic reaction to a previous dose of hepatitis B vaccine.
- you/your child have/has a severe infection with high temperature (above 38 °C). A minor infection such as a cold should not be a problem, but talk to your doctor about this before being vaccinated.

Please also tell your doctor if

- you/your child experienced any problems after a previous vaccination with ENGERIX-B or another vaccine (including a high temperature of 40 °C and more without an identifiable cause within 48 hours of vaccination; collapse or shock-like state within 48 hours of vaccination; persistent, inconsolable crying or screaming lasting ≥ 3 hours within 48 hours of vaccination; seizures with or without a fever within 3 days of vaccination).
- you/your child have/has a blood clotting disorder or bruise(s) easily.
- you/your child are/is taking or has recently taken any other medicines (or any other vaccine).
- you/your child have/has a personal or family history of any allergy.
- you/your child are/is pregnant or if you suspect you/your child may be pregnant.
- you/your child are/is breast-feeding.

If you/your child have/has a low blood platelet count or a tendency to bleeding, ENGERIX B should be administered with caution since bleeding may occur following intramuscular administration. Firm pressure (without rubbing) should be applied to the injection site for at least 2 minutes. The vaccine may be administered by subcutaneous injection in such cases.

If necessary, the doctor will determine the right time and vaccination regimen for you/your child.

Take special care with ENGERIX-B

Due to the long incubation period (time of infection to onset of the disease) of hepatitis B, it is possible for an unrecognised infection to be present at the time of immunisation. In such cases, a vaccination may not be able to prevent the hepatitis B disease from developing.

Vaccination with ENGERIX B will not prevent infections caused by other pathogens known to damage the liver such as hepatitis A, hepatitis C and hepatitis E viruses.

As with any vaccine, sufficient immune response may not be induced in all vaccinated persons. A number of factors, such as male gender, obesity, smoking, route of administration and some chronic underlying diseases affect the immune response to hepatitis B vaccines. Consideration should be given to serological testing of those subjects who may be at risk from not achieving sufficient seroprotection following a complete vaccination course.

The administration of additional vaccine doses may need to be considered for persons who do not respond or have a sub-optimal response to the vaccination course.

In HIV infected patients, as well as in patients with renal insufficiency, including patients undergoing haemodialysis, and in persons with an impaired immune system, adequate levels of antibodies may not be obtained after the primary immunisation course. Such patients may therefore require administration of additional doses of vaccine.

Please speak with your doctor about this, if necessary.

Patients with chronic liver disease, or with HIV infection, or hepatitis C carriers should not be precluded from vaccination against hepatitis B. Vaccination is advisable since hepatitis B can be severe in these patients. The doctor should therefore consider hepatitis B vaccination on a case-by-case basis in such patients.

Using ENGERIX-B with other medicines or vaccines

Please tell your doctor or pharmacist if you/your child are/is taking or have/has recently taken any other medicines, including medicines obtained without a prescription or if you/your child received another vaccine recently.

The simultaneous administration of Engerix B and a standard dose of HBIG (hepatitis B immunoglobulins) does not result in lower anti-HBs antibody titres provided that the injections are administered at separate injection sites.

ENGERIX B can be given concomitantly with haemophilus influenzae b, BCG (tuberculosis), hepatitis A, polio, measles, mumps, rubella, diphtheria, tetanus and pertussis vaccines.

Engerix B may be used to complete a primary immunisation course started either with plasma-derived or with other genetically-engineered hepatitis B vaccines. If a booster vaccination is desired, ENGERIX B may also be administered to persons who have previously received a primary immunisation course with plasma-derived or with other genetically-engineered hepatitis B vaccines.

As with any vaccine, a sufficient immune response may not be achieved in persons with immunodeficiency disease or by those undergoing therapy that weakens the immune system.

POSSIBLE SIDE EFFECTS

Common (affects 1 to 10 out of 100 people):

- Pain or discomfort at the injection site
- Hardening of the tissue or redness at the injection site

These common side effects generally subside within a few days.

Rare (affects 1 to 10 out of 10,000 people):

- Diarrhoea, nausea, stomach pain, vomiting
- Influenza-like symptoms, fever (above 38 °C), tiredness, feeling unwell
- Joint and muscle pain
- Dizziness, headache, paraesthesia e.g. tingling, prickling skin sensation
- Abnormal liver function tests (e.g. increased liver enzymes)
- Itching, rash, hives

Very rare (affects fewer than 1 out of 10,000 people, including isolated cases):

- Increased tendency to bleeding or bruising caused by a reduction in blood platelets
- Vascular inflammation
- Joint inflammation
- Swelling of the lymph nodes
- Low blood pressure and fainting
- Central and peripheral nervous system disorders, signs of paralysis, nerve inflammation including ascending paralysis (Guillain Barré syndrome), inflammation of the optic nerves (optic neuritis), multiple sclerosis, inflammatory and non-inflammatory diseases of the brain (meningitis, encephalitis, encephalopathy) and seizures
- Allergic reaction, anaphylactic shock (usually within a very short time following injection of the vaccine):
 - Localised or extensive itchy or blistering skin rash (erythema multiforme)
 - Facial swelling, including around the eyes
 - Difficulty in breathing (bronchospasm) or swallowing
 - Sudden drop in blood pressure and loss of consciousness