For optional vaccination

Vaccination of hepatitis B vaccine (Heptavax®-II)

Before having vaccinated with the hepatitis B, it is necessary to know the physical condition of the recipients. Therefore, please fill in the screening questionnaire items as completely as possible. In the case of children, their parents etc. who have grasped their health condition should fill in this sheet.

○Characteristics and side reactions of vaccine

This is a hepatitis B vaccine produced by utilizing the recombinant gene technology. In general, vaccination is conducted 3 times, that is, initial time, after 1 month (after 4 weeks from initial vaccination), after 6 months (after 20-24 weeks from initial vaccination), for prevention of hepatitis B.
Major side reactions are pain of the injection site, redness, pruritus (itching), swelling (puffiness), induration (lump), hot feeling, fever, malaise, ataxia of hand, etc. In very rare cases, shock, anaphylaxis-like symptoms (blood pressure decrease, dyspnea, facial pallor, etc.), multiple sclerosis, acute disseminated encephalomyelitis, myelitis, optic neuritis, Guillain-Barre syndrome and peripheral nerve disorder may occur. If you become aware of anything abnormal, you should immediately notify a doctor.

○ Those who correspond to the following should not receive vaccination.

1. You definitely have fever. (Fever of above 37.5°C in general)
2. You definitely have a serious acute disease.
3. Those who have definitely suffered anaphylaxis by an ingredient of this drug (ask the doctor for details)
4. In addition to the above, you are in the condition unacceptable for vaccination.

○ Those who correspond to the following should consult a doctor before vaccination.

1. Those with underlying diseases such as cardiovascular disease, renal disease, hepatic disease, blood disease, growth disorder, etc.
2. Those who have had fever or demonstrated a symptom suggesting allergic reaction including systemic rash, etc. within 2 days after vaccination
3. Those who have a history of convulsion in the past
4. Those who have been diagnosed to have immunodeficiency in the past and those whose close relative has congenital immunodeficiency
5. Those who may have a risk of allergic reaction to an ingredient of this drug (ask the doctor for detail).
6. Women who are pregnant or possibly pregnant

○Simultaneous vaccination with other vaccine(s)

Simultaneous vaccination with other type of vaccine(s) is permitted if considered necessary by a doctor.

○Cautions after vaccination

1. An acute side reaction such as anaphylaxis, etc. may occur within 30 minutes after vaccination. Therefore, you should remain in the medical organization, etc. and observe your condition so as to immediately contact the doctor.
2. Please avoid high-intensity exercise on the day of vaccination. (You can bathe on the day of vaccination but do not scratch the injected site.)
3. Sometimes you have fever, or the vaccinated site becomes swollen or turns red after vaccination. However, these symptoms are generally mild and disappear within several days.
4. You should pay attention to your health control after vaccination, and if you notice high fever, change in physical condition, or localized abnormal reaction, you should immediately consult a physician.

Planned vaccination date	__ (day) __ (month) (About____ :_____	**Name of medical organization**	

[Reference]
When any health damage occurs due to the hepatitis B vaccination, it is sometimes possible to receive treatment expenses, etc. according to Relief System for Sufferers from Adverse Drug Reactions.
For details, please refer to the homepage, etc. of Pharmaceuticals and Medical Devices Agency.
[Relief System for Sufferers from Adverse Drug Reactions]
This is a system to pay medical expenses, medical care, disability pension as a benefit so as to relieve those who have suffered health damage such as a disease, disorder, etc. that require hospitalization for the treatment of adverse reaction despite the appropriate usage of drugs. In such case, medical certificate and medication certificate, etc. become necessary. It is advisable to consult Pharmaceuticals and Medical Devices Agency if you wish to request for relief benefit.

For inquiry, please contact the following.
Adverse drug reaction relief system consultation window, Pharmaceuticals and Medical Devices Agency
Telephone: 0120−149−931 (toll-free) URL: https://www.pmda.go.jp/kenkouhigai_camp/index.html

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Screening questionnaire for vaccination with Hepatitis B vaccine (HEPTAVAX®-II) (for optional vaccination)

***To those who wish to have vaccination or to the parents, etc.: Please fill in the thick-framed boxes as completely as possible.**

KANA or Phonetics		**M / F**	**Body temperature before examination:**	__.__ ºC
Name of person receiving vaccination			**Date of birth**	Born in __(month) ____(year)__ (__ years __month(s) old)
			Address:	
(Parent's name)			**Phone No.:**	( ) -

*** Please fill in all of the thick-framed answer columns.**

Questionnaire	Column for answer		Physician's comments
1. Have you read and understood the explanation about hepatitis B vaccination you are going to receive today?	No	Yes	
2. How many times have you received hepatitis B vaccine??	(__th) time		
3. Do you have any unfavorable condition today? Please describe the symptom concretely. ( )	Yes	No	
4. Have you been ill within the past month? Disease name ( )	Yes	No	
5. Has any one of your family members been sick with measles, rubella, chickenpox, mumps, etc. within the past 1 month? Disease name ( )	Yes	No	
6. Have you received any vaccination within the past 1 month? Vaccination ( )	Yes	No	
7. Have you ever had any particular disease (disease of cardiovascular system, kidney and liver, blood disease, growth disorder, immunodeficiency, other disease) and has received treatment by a doctor? Disease name ( )	Yes	No	
Did the doctor treating the above-mentioned disease say you can receive the vaccination today?	Yes	No	
8. Have you ever developed convulsion? (About ____ month ____ year the last time))	Yes	No	
Did you have a fever then?	Yes	No	
9. Have you ever developed drug-/food- related exanthema/urticaria or showed an unfavorable condition?	Yes	No	
10. Has any of your close relatives been diagnosed to have congenital immunodeficiency?	Yes	No	
11. Have you ever felt sick after receiving vaccination? Name of vaccination/symptom ( )	Yes	No	
12. Has any one of your close relatives become sick after vaccination?	Yes	No	
13. (In the case of children) Was any abnormality found during the delivery, at the time of birth, in the health checkup of infants, etc.? If yes, describe concretely. ( )	Yes	No	
14. (In the case of female) Are you pregnant at present?	Yes	No	
15. Do you have any question about the vaccination today?	Yes	No	
16. Other than the above, if you wish to convey anything about the health condition, please describe concretely.			

17. Physician's comments

Based on the above questioning and examination, the vaccination today is (possible / has to wait)

The effect and side reaction of vaccination and the relief based on Pharmaceuticals and Medical Devices Agency Law was explained to the recipient (or his/her parent).

Signature of doctor _____

The doctor examined you and explained you about the effect, purpose, and risk of serious side reaction of vaccination as well as the relief based on the Act on Pharmaceuticals and Medical Devices Agency. After you have understood the explanation, do you still wish to receive vaccination?

(I want vaccination / I don't want vaccination)

Signature of person in question (or his/her parent, etc.) _____

Name of vaccine used		Dosage and administration	Site, name of doctor, vaccination date	
HEPTAVAX®-II (Recombinant adsorbed hepatitis B vaccine (derived from yeast))		□0.25mL (under 10 years old) [Subcutaneous only] □0.5mL (10 years old or older) [Subcutaneous or intramuscular]	Site	
Name of manufacturer	MSD KK		Name of doctor	
Lot. No. Medical record No.			Vaccination date	/ / / (d/m/y)
Note: Confirm that the effective period has not been expired.				

The private information you have stated will be used only for the preliminary examination of vaccination.