Application Form/Pre-examination Form for IMOVAX POLIO® Subcutaneous Injection

For optional vaccination

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To physicians who administer IMOVAX POLIO® Subcutaneous Injection

Information on IMOVAX POLIO® Subcutaneous Injection

Concerning transmissible spongiform encephalopathy (TSE)

As specified at the top and in "2. Important Precautions" section of the package insert, IMOVAX POLIO® Subcutaneous Injection uses the bovine serum originated in the U.S., Canada, and Australia during manufacturing processes. Although a risk of contracting transmissible spongiform encephalopathy (TSE) by administration of this product is theoretically very low, necessity for injection should be carefully reviewed prior to its use and explanation should be given to a vaccinee and his/her guardian as part of informed consent.

The following written explanation and a pre-examination form were prepared as an explanation material to be used for obtaining informed consent and for confirming the pre-injection conditions of a vaccine.

Excerpts of package insert

[Top of main text]

This product uses bovine derived ingredient (bovine serum originated in the U.S., Canada, and Australia) during manufacturing processes. Although a risk of contracting transmissible spongiform encephalopathy (TSE) by administration of this product is theoretically very low, this product should be administered in consideration of the necessity for its use (see "2. Important Precautions").

[2. Important Precautions in [Precautions of vaccination] (excerpt)]

(4) This product uses the bovine serum originated in the U.S., Canada, and Australia as the medium ingredient during seed adjustment, cell bank adjustment, and cell culture process. The ingredient is obtained from healthy bovine, and goes through dilution and elimination processes (purification and filtration) during manufacturing processes. Based on the theoretical risk analysis, this product was confirmed to satisfy the predetermined safety criteria. Contraction of transmissible spongiform encephalopathy (TSE) by administration of this product has not been reported overseas. The risk of contraction of transmissible spongiform encephalopathy (TSE) is therefore considered very small, but the risk should be explained to vaccinees and their guardians.

Optional vaccination

To Persons Who Desire the Inoculation of Inactivated Polio Vaccine

Read this leaflet carefully. It contains information indispensable for the vaccination

1. Polio (poliomyelitis)

(1) Polio (poliomyelitis) is acute viral infection caused by poliovirus and induces acute flaccid paralysis.

(2) Poliovirus is classified into three types (types 1, 2, and 3) according to antigenicity.

(3) Even when infected with poliovirus, inapparent infection occurs in most patients (reported to be 90% or higher). A patient with mild infection is known to recover merely with an occurrence of mild cold symptoms or gastrointestinal symptoms. However, a serious patient may die due to respiratory muscle paralysis or bulbar paralysis, and persistent sequelae such as muscle weakness, muscle tone decreased, and muscle atrophy remain.

(4) Occurrences of polio are reported to be one in 200 infected persons. The latent period from virus infection up to the onset of paralysis varies between 3 days and one month, but is usually between 4 to 10 days.

(5) Due to unavailability of therapeutic drug for polio, it is important to prevent polio infection and epidemic by vaccination.

2. Inactivated polio vaccine for prevention of infectious diseases caused by polio virus

(1) Inactivated polio vaccine is a 3-valent vaccine. It contains the following 3 types of virus as active ingredients: 40 D-antigen unit of inactivated polio virus type 1 (Mahoney strain), 8-unit inactivated polio virus type 2 (MEF-1 strain), and 32-unit inactivated polio virus type 3 (Saukett strain).

(2) Inactivated polio vaccine is administered 3 times for the initial standard immunization starting with the age of 3 months with intervals of 3 weeks. More than 6 months after the initial immunization, the first booster dose (extra vaccination) is administered.

(3) While these initial vaccination and booster doses of inactivated polio vaccine show sufficient immunogenicity (power of protection from infections), the power shall decline over time.

(4) Studies involving children aged 4-6 years old show that a second booster dose increased immunogenicity on the decline.

(5) After inoculation of the inactivated polio vaccine, side reactions similar to those observed with inoculation of other vaccines may be found. However, they are usually transient and disappear in several days. The most frequently observed side reactions are redness and swelling at injection site. Furthermore, fever develops in several percent of vaccinees. The following serious adverse reactions have been reported: (1) Shock and anaphylaxis (2) convulsion

(6) Bovine derived ingredients (bovine serum originated in cattle of US, Canada, and Australia) are used in the early manufacturing stage of this vaccine. However, the product goes through subsequent purification processes. This vaccine has already been used in not less than 86 countries worldwide, and approximately 270 million doses of this vaccine have been marketed between January 1993 and June 2011. However, there is no report of occurrence of TSE due to inoculation of this vaccine. Therefore, a risk of contracting transmissible spongiform encephalopathy (TSE) is very low for a person receiving this vaccine although a theoretical risk may not be denied.

3. The following persons should not receive the inoculation:

(1) Person with an obvious fever (usually >37.5°C).

(2) Person affected by a severe acute disease.

(3) Person with a history of anaphylaxis (severe allergic reactions such as breathing difficulty and urticaria of the whole body that usually develop within 30 minutes after inoculation) due to the ingredient of this vaccine.

(4) Person who was advised by his/her personal physician not to receive the polio vaccine.

4. The following persons should consult the physician before the inoculation:

(1) Person with underlying diseases such as cardiovascular disorder, renal disorder, hepatic disorder, hematologic disorder, and growth impairment.

(2) Person with a history of symptoms suspected of allergy such as fever and systemic rash within 2 days of the past vaccination.

(3) Person who has developed convulsions (seizures) in the past.

(4) Person in whom an immune abnormality was pointed out in the past or who has a close relative with congenital immunodeficiency.

(5) Person who may develop allergic reactions to the ingredient of this vaccine.

(6) Person with a medical history of allergy to polypeptide and aminoglycoside antibiotics (these antibiotics are used during manufacture of the vaccine).

5. Pay attention to the following points after inoculation:

(1) Be ready to make immediate contact with the physician for 30 minutes after inoculation because shock and anaphylaxis may develop.

(2) Immediately seek medical attention when abnormalities such as high fever and convulsion develop after inoculation.

(3) Pay attention to physical condition for one week after inoculation. Consult a physician when swelling of the inoculation site is notable or your child becomes ill-tempered after inoculation.

(4) An interval of ≥6-day should be provided before receiving another vaccine following inoculation of this vaccine. However, simultaneous vaccination is possible for this vaccine, so consult a physician when it is desired.

(5) Keep the inoculation site clean. The vaccinee may take a bath, but rubbing the injection site should be avoided.

(6) Avoid vigorous exercise on the day of inoculation. Other than that, your child can lead an ordinary life.

Have your child medically examined after filling in the "Application form/preliminary examination form for inactivated polio vaccine". When you have noticed anything unusual, consult a physician.
When health injury is caused by inoculation of inactivated polio vaccine, financial support for the treatment may be provided in accordance with the "Relief System for Sufferers from Adverse Drug Reactions." Please see the website of the Pharmaceuticals and Medical Devices Agency for details.

Scheduled date of inoculation	MMDDYY ( ) o'clock	Name of medical institution	

<Copy for medical institution>

Application Form/Preliminary Examination Form for Inactivated Polio Vaccine

For arbitrary vaccination

* Please fill in within the heavy-line frame or circle an appropriate answer.

			Body temperature before medical checkup	
Address			TEL ( ) -	
(Kana) Name of vaccinee	( )	Male/ Female	Date of birth	(years, month)
Name of guardian (when the vaccinee is under 20 years old)				

Question	Answer		Physician's comment
Has your child ever received polio vaccine?	Timing ( ) Number of vaccination ( )		
(Please answer the following questions when the vaccinee is an infant.)			
Body weight at birth ( ) g Did your child have any abnormal findings at delivery?	Yes	No	
Did your child have any abnormal findings after birth?	Yes	No	
Has your child ever been indicated to have an abnormality in a medical checkup for infants?	Yes	No	
Is there anything wrong with your child today? Symptoms ( )	Yes	No	
Has your child been ill in the past 1 month? Name of disease ( )	Yes	No	
Was there any family member or friend of your child who was sick with measles, rubella, vericella (chickenpox), and mumps within the past month? Name of disease ( )	Yes	No	
Was your child vaccinated in the past month? Name of vaccination ( )	Yes	No	
Has your child been receiving medical treatment for a special disease (congenital abnormality, heart disease, renal disease, liver disease, blood disease, neurologic disease, immunodeficiency, and other disease) up to now? Name of disease ( )	Yes	No	
Has the physician treating your child approved vaccination today?	No	Yes	
Has your child ever developed seizure (convulsion)? Approximately ( ) years old	Yes	No	
If yes, did your child have fever at that time?	Yes	No	
Has your child ever developed rash or urticaria, or become ill as a reaction to medications or foods? Medications or foods ( )	Yes	No	
Is there any close relative who was diagnosed as congenital immunodeficiency?	Yes	No	
Has your child ever become ill after receiving a vaccine? Name of vaccination ( )	Yes	No	
Is there any close relative who become ill after receiving a vaccine?	Yes	No	
Has your child received blood transfusion or the injection of gamma globulin in the past 6 months?	Yes	No	
Did you read and understand the explanation material about the vaccination that will be administered today (including an explanation on the use of bovine-derived ingredient)?	No	Yes	
Do you have any question about the vaccination today?	Yes	No	

Physician's comment
Based on the above answers and the results of the medical examination, I consider that the child (can/cannot) receive vaccination today. I have explained to the guardian/vaccinee the information concerning the benefits and side effects of vaccination, the use of bovine-derived ingredient and the Relief Services for Adverse Health Effects. Signature or name and seal of physician [ ]
Guardian/vaccinee's comment
I received the medical examination and was given explanation by the physician including the use of bovine-derived ingredient and understand the effects and side effects of the vaccination. I (agree/do not agree) to receive the inoculation. Please circle either of them. Signature of guardian/vaccinee [ ]

Name of vaccine used (a sticker attached to the outer box indicating manufacturing No. may be attached below)	Dose	Place/name of physician/date of inoculation
Name: Inactivated polio vaccine (Salk vaccine) Name of manufacturer: Sanofi Manufacturing No.:	Subcutaneous inoculation:0.5 mL Inoculation Site: Extensor side of left/right arm	Name of medical institution: Name of physician: Date of inoculation: MMDDYY, ( ) o'clock

The purpose of this preliminary examination form is to ensure the safety of the vaccination.
The confidential information provided above is used only for the preliminary examination on the vaccination.

<Copy for guardian/vaccinee>

Application Form/Preliminary Examination Form for Inactivated Polio Vaccine

For arbitrary vaccination

* Please fill in within the heavy-line frame or circle an appropriate answer.

			Body temperature before medical checkup	
Address			TEL ( ) -	
(Kana) Name of vaccinee	( )	Male/ Female	Date of birth	(years, month)
Name of guardian (when the vaccinee is under 20 years old)				

Question	Answer		Physician's comment
Has your child ever received polio vaccine?	Timing ( ) Number of vaccination ( )		
(Please answer the following questions when the vaccinee is an infant.)			
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Did your child have any abnormal findings after birth?	Yes	No	
Has your child ever been indicated to have an abnormality in a medical checkup for infants?	Yes	No	
Is there anything wrong with your child today? Symptoms ( )	Yes	No	
Has your child been ill in the past 1 month? Name of disease ( )	Yes	No	
Was there any family member or friend of your child who was sick with measles, rubella, vericella (chickenpox), and mumps within the past month? Name of disease ( )	Yes	No	
Was your child vaccinated in the past month? Name of vaccination ( )	Yes	No	
Has your child been receiving medical treatment for a special disease (congenital abnormality, heart disease, renal disease, liver disease, blood disease, neurologic disease, immunodeficiency, and other disease) up to now? Name of disease ( )	Yes	No	
Has the physician treating your child approved vaccination today?	No	Yes	
Has your child ever developed seizure (convulsion)? Approximately ( ) years old	Yes	No	
If yes, did your child have fever at that time?	Yes	No	
Has your child ever developed rash or urticaria, or become ill as a reaction to medications or foods? Medications or foods ( )	Yes	No	
Is there any close relative who was diagnosed as congenital immunodeficiency?	Yes	No	
Has your child ever become ill after receiving a vaccine? Name of vaccination ( )	Yes	No	
Is there any close relative who become ill after receiving a vaccine?	Yes	No	
Has your child received blood transfusion or the injection of gamma globulin in the past 6 months?	Yes	No	
Did you read and understand the explanation material about the vaccination that will be administered today (including an explanation on the use of bovine-derived ingredient)?	No	Yes	
Do you have any question about the vaccination today?	Yes	No	

Physician's comment
Based on the above answers and the results of the medical examination, I consider that the child (can/cannot) receive vaccination today. I have explained to the guardian/vaccinee the information concerning the benefits and side effects of vaccination, the use of bovine-derived ingredient and the Relief Services for Adverse Health Effects. Signature or name and seal of physician [ ]
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I received the medical examination and was given explanation by the physician including the use of bovine-derived ingredient and understand the effects and side effects of the vaccination. I (agree/do not agree) to receive the inoculation. Please circle either of them. Signature of guardian/vaccinee [ ]

Name of vaccine used (a sticker attached to the outer box indicating manufacturing No. may be attached below)	Dose	Place/name of physician/date of inoculation
Name: Inactivated polio vaccine (Salk vaccine) Name of manufacturer: Sanofi Manufacturing No.:	Subcutaneous inoculation:0.5 mL Inoculation Site: Extensor side of left/right arm	Name of medical institution: Name of physician: Date of inoculation: MMDDYY, ( ) o'clock

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