

**Quadrivalent meningococcal vaccine  
(Tetanus toxoid conjugate)**

**MenQuadfi<sup>®</sup> Intramuscular Injection**

**Vaccination application form/preliminary  
examination sheet**

**For voluntary vaccination**

This booklet provides information on the quadrivalent meningococcal vaccine to those who are willing to receive the vaccination and includes two copies of the vaccination application form/preliminary examination sheet (one for the medical institution, and the remaining copy for the person receiving the vaccine or their guardian).

Sanofi K.K

## **To persons who are willing to receive quadrivalent meningococcal vaccine**

- This is important information about vaccination. Please make sure to read it. -

### **1. About invasive meningococcal diseases (IMD)**

- 1) IMD refers to infections caused by invasion of *Neisseria meningitidis* into the spinal fluid or blood.
- 2) *Neisseria meningitidis* is classified into at least 12 different serogroup. Groups A, B, C, Y and W are mainly isolated from IMD cases. *Neisseria meningitidis* is only isolated from humans.
- 3) According to National Surveillance in Japan(2013-2019), 20-50 cases are diagnosed with IMD every year, while overseas more than 300,000 people are diagnosed with IMD and approximately 30,000 people die from IMD. The incidence of IMD is higher in sub- Saharan Central Africa, which is called the meningitis belt, and occurs sporadically in developed countries. The incidence of IMD is also higher during colder seasons in the temperate zone and during dry seasons in the tropical zone.
- 4) The risk of IMD is highest among teenagers living together, for example in student dormitories. If IMD occurs among such people, taking appropriate action to prevent the spread of IMD will be important.
- 5) IMD is transmitted through the adherence of *Neisseria meningitidis* in airborne droplet through coughing or sneezing, or others to the oral or nasal mucosa or through direct contact with the saliva of patients with IMD through kissing or sharing a cup, glass or bottle.
- 6) When infected *Neisseria meningitidis* adheres to the oral or nasal mucosa, IMD will remain latent (inapparent infection) or will present with acute symptoms. The latent period is 2 to 10 days (4 days on average), and cold- like symptoms are seen during this period. *Neisseria meningitidis* enters from the mucosa to the blood and causes bacteremia, sepsis or cerebrospinal meningitis. Babies and children develop fever, vomiting or other symptoms mainly and may have a bulging anterior fontanelle. Dot hemorrhages in ocular mucosa, oral mucosa, perioral mucosa or skin, hemorrhagic macules on the body or legs may be observed.
- 7) Fulminant symptoms, including headache, severe fever, hypotension, convulsions and disturbed consciousness, are observed, along with hemorrhagic macules on the skin or mucosa, and may cause fatal shock within a few hours to a few days of onset. Upper respiratory inflammation, pneumonia, arthritis, otitis media, epiglottitis, conjunctivitis, vaginitis, cervicitis or other various symptoms have also reported.
- 8) The risk of IMD is higher in asplenic patients, those who have undergone a spleen resection, patients with complement deficiency (especially, C3, C5- C9 deficiency), patients on immunosuppressant therapy and HIV- infected patients.
- 9) Antimicrobial agents are effective for IMD and it may be cured with early appropriate treatment. If necrosis occurs in the hands or feet, amputation may be needed.

### **2. About a quadrivalent meningococcal vaccine MenQuadfi® Intramuscular Injection**

- 1) The vaccine is used to prevent IMD caused by Group A, C, Y or W *Neisseria meningitidis*.

- 2) The vaccine cannot completely prevent infections, like other vaccines. The vaccine prevents the aggravation of infections and transmission of infections to other people.
- 3) The vaccine contains tetanus toxoid. However, the vaccine is not for protecting against tetanus.
- 4) A dose of 0.5 mL is injected intramuscularly.
- 5) Side effects may occur after the injection of the vaccine, as is sometimes observed after the injection of other vaccines. However, side effects are normally temporary and resolve within a few days after vaccination. Common side effects include pain at the injection site, muscle pain, fatigue and headache. Also, the following severe side effects have been reported overseas: vasovagal reflex-associated fainting, shock, anaphylaxis, acute disseminated encephalomyelitis (ADEM), Guillain-Barre syndrome, transverse myelitis, convulsion and facial nerve paralysis.

### **3. Those who are not allowed to receive the vaccine**

- 1) Those who have a fever ( $>37.5^{\circ}\text{C}$ )
- 2) Those who have serious acute diseases
- 3) Those who have ever developed anaphylaxis to ingredients of the vaccine or tetanus toxoid (anaphylaxis: severe allergic reactions that are usually seen within 30 minutes after vaccination and are complicated with respiratory difficulty or systemic urticarial)
- 4) Those who the personal physician determines as not suitable for receiving the vaccine

### **4. Those who should discuss vaccination with a physician before receiving the vaccine**

- 1) Those who have underlying disease as cardiovascular diseases, kidney diseases, liver diseases, blood diseases, development disorders or others
- 2) Those who have previously developed fever, systemic rash or other symptoms suspected of indicating allergy within 2 days after vaccination
- 3) Those who have previously experienced convulsions (seizures)
- 4) Those who have previously been diagnosed with immune disorders or have relatives with congenital immunodeficiency
- 5) Those who may develop allergies to ingredients of the vaccine or tetanus toxoid
- 6) Those with low platelet counts (thrombocytopenia) or are prone to hemorrhage
- 7) Those who have previously been diagnosed with Guillain-Barre syndrome

### **5. Things you should or should not do after vaccination**

- 1) Psychological stress caused by the injection of the vaccine may cause vasovagal reflex-associated fainting immediately after or sometime after the injection. To prevent falls due to fainting, you will be asked to rest on a chair or sofa with a backrest for approximately 30 minutes after the injection. Please tell the physician giving the injection or the nurse immediately if you feel sick while you are resting.
- 2) Please visit a physician immediately if severe fever or convulsions occur after vaccination.
- 3) You may concomitantly receive this vaccine and other vaccines. If you want to do so, please discuss this with a physician.

- 4) Please keep the injection site clean. You can take a bath or a shower, but you must not rub the injection site.
- 5) On the day of vaccination, you can engage in ordinary activities, except for hard exercise.
- 6) Please watch your health for 1 week after the vaccination. Please talk to a physician if you experience pain or feel tired for a long period of time after the vaccination. Even if you experience these symptoms overseas, please visit a medical institution immediately. If you did not visit a medical institution overseas, please report it to the medical institution where you received the vaccine or your personal physician and undergo an examination as necessary.

Please fill out the quadrivalent meningococcal vaccine MenQuadfi® Intramuscular Injection vaccination application form/preliminary examination sheet and request a consultation. Please notify the physician if you feel that there is something wrong with you.

If you suffer from any health damages after receiving the vaccine, you may be able to receive treatment cost etc. in accordance with the Relief System for Sufferers from Adverse Drug Reactions. For details regarding the relief system, please see the website for the Pharmaceuticals and Medical Devices Agency.

Scheduled date/time of vaccination		Name of medical institution	
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&lt; For the medical institution &gt;

**For voluntary vaccination****Vaccination application form/preliminary examination sheet**

\*Please fill out the space framed by a thick black line or circle the appropriate answer.

		<b>Body temperature before examination</b>		°C	
<b>Address</b>		Telephone:			
<b>Name of the person receiving the vaccine</b>		Male/ Female	<b>Date of birth</b>	Month/	day/
(if the person above is a minor) <b>Name of the guardian</b>				(Age: year	year month)

Question	Answer		For physician use
Have you read and understood the explanatory document and booklet about the vaccine?	No	Yes	
Have you ever received a meningococcal vaccine?	No	Yes	
Do you feel sick or feel like something is wrong with your body? Symptoms ( )	Yes	No	
Did you experience any diseases during within a month? Disease ( )	Yes	No	
Did you receive any other vaccines during within a month? Vaccine ( )	Yes	No	
Have you ever suffered from any serious illness (e.g., any congenital disease, heart/kidney/liver/blood/cranial nerve disease, immunodeficiency or other diseases and been treated by a doctor? Disease ( )	Yes	No	
Does your treating physician agree that you may receive the vaccine?	No	Yes	
Have you ever experienced convulsions? (if yes, how old were you: years old)	Yes	No	
Did you have a fever at that time?	Yes	No	
Have you ever developed rashes or urticaria or felt sick after taking any drugs or food? Drug/food ( )	Yes	No	
Do you have any relatives who have been diagnosed with congenital immunodeficiency?	Yes	No	
Have you ever felt sick after receiving a vaccine? Vaccine ( )	Yes	No	
Do you have any relatives who have felt sick after receiving a vaccine?	Yes	No	
Are you pregnant or likely to be pregnant (a missed period)?	Yes	No	
Have you ever felt sick after an injection, blood donation or other medical interventions wherein a needle was used or have you ever been diagnosed with vasovagal reflex?	Yes	No	
Do you have any questions about the vaccine?	Yes	No	

**For physician use**

Based on the results of the interview and examination above, I have determined that the person above (can/cannot) receive the vaccine. I have explained the efficacy and possible side effects of the vaccine and the relief system under the law of the Pharmaceuticals and Medical Devices Agency. to the person above or their guardian.

**Physician's signature or seal ( )**

**For the guardian**

I underwent a consultation or received an explanation about the vaccine and understand the efficacy and possible side effects of the vaccine. Do you agree that the information and do you want your child to receive the vaccine? (Yes/No)

**Guardian's signature ( )**

Vaccine (The serial number seal on the box can also be attached instead.)	Dosage/administration	Medical institution/physician/date of vaccination
Name: quadrivalent meningococcal vaccine (tetanus toxoid conjugate vaccine) Manufacturer: Sanofi Serial number:	Intramuscular injection 0.5 mL Injection site Left/Right Deltoid Left/Right Anterior thigh	Medical institution: Physician: Date/time of vaccination:

The preliminary examination sheet is used to ensure the safety of the vaccination

The personal information above is only used for the preliminary examination for vaccination.

&lt; For the person receiving the vaccine or their guardian &gt;

**For voluntary vaccination****Vaccination application form/preliminary examination sheet**

\*Please fill out the space framed by a thick black line or circle the appropriate answer.

		<b>Body temperature before examination</b>		°C	
<b>Address</b>		Telephone:			
<b>Name of the person receiving the vaccine</b>		Male/ Female	<b>Date of birth</b>	Month/ (Age: year	day/ year
(if the person above is a minor) <b>Name of the guardian</b>				year	month)

Question	Answer		For physician use
Have you read and understood the explanatory document and booklet about the vaccine?	No	Yes	
Have you ever received a meningococcal vaccine?	No	Yes	
Do you feel sick or feel like something is wrong with your body? Symptoms ( )	Yes	No	
Did you experience any diseases during within a month? Disease ( )	Yes	No	
Did you receive any other vaccines during within a month? Vaccine ( )	Yes	No	
Have you ever suffered from any serious illness (e.g., any congenital disease, heart/kidney/liver/blood/cranial nerve disease, immunodeficiency or other diseases and been treated by a doctor? Disease ( )	Yes	No	
Does your treating physician agree that you may receive the vaccine?	No	Yes	
Have you ever experienced convulsions? (if yes, how old were you: years old)	Yes	No	
Did you have a fever at that time?	Yes	No	
Have you ever developed rashes or urticaria or felt sick after taking any drugs or food? Drug/food ( )	Yes	No	
Do you have any relatives who have been diagnosed with congenital immunodeficiency?	Yes	No	
Have you ever felt sick after receiving a vaccine? Vaccine ( )	Yes	No	
Do you have any relatives who have felt sick after receiving a vaccine?	Yes	No	
Are you pregnant or likely to be pregnant (a missed period)?	Yes	No	
Have you ever felt sick after an injection, blood donation or other medical interventions wherein a needle was used or have you ever been diagnosed with vasovagal reflex?	Yes	No	
Do you have any questions about the vaccine?	Yes	No	

**For physician use**

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**Physician's signature or seal ( )**

**For the guardian**

I underwent a consultation or received an explanation about the vaccine and understand the efficacy and possible side effects of the vaccine. Do you agree that the information and do you want your child to receive the vaccine? (Yes/No)

**Guardian's signature ( )**

Vaccine (The serial number seal on the box can also be attached instead.)	Dosage/administration	Medical institution/physician/date of vaccination
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