About the vaccination with 23-valent pneumococcus vaccine (Pneumovax® NP)

Before vaccination with 23-valent pneumococcus vaccine (Pneumovax® NP), it is essential to know the physical condition of the recipient. Please carefully read the following information regarding 23-valent pneumococcus vaccine (Pneumovax® NP) and fill out the attached screening questionnaire as completely as possible. If you have difficulty in filling out the necessary information, your designated immediate contact (for example a family member) may complete the form. Please understand that vaccination cannot be performed if the recipient does not provide informed consent.

● Vaccine effects and potential adverse reactions

The 23-valent pneumococcus vaccine (Pneumovax® NP) can be administered to people aged 2 years and older who are at high risk of contracting a serious disease as a result of pneumococci. The vaccine produces antibodies to 23 types of pneumococci and is expected to prevent infections caused by these types of pneumococci.
The most common adverse reactions seen in clinical trials were local reactions at the injection site (pain, redness, swelling, and itching), headache, and armpit pain. Very rarely, the following adverse reactions were observed: anaphylactoid reaction; thrombocytopenia; acute radiculopathy such as paresthesia and Guillain-Barre syndrome; cellulitis; cellulitis-like reactions; injection site necrosis, and injection site ulcer.
Please contact your physician immediately if any such abnormalities are experienced following vaccination.

● Those ineligible for vaccination

1. You are under 2 years old.
2. You have a fever (higher than 37.5°C).
3. You definitely have a serious acute disease.
4. You have a confirmed history of anaphylaxis to the components of this drug (please ask your physician for details).
5. If you are deemed inappropriate to receive the vaccination by your physician.

● Those who need to consult a physician prior to vaccination

1. If you definitely have underlying diseases such as cardiovascular/kidney/liver/blood diseases and development disorder.
2. If you have a history of fever within 2 days after vaccination, or symptoms such as systemic exanthema, suggesting allergy.
3. If you have a history of convulsion.
4. If you have been diagnosed to have immunodeficiency or if your close relative has congenital immunodeficiency.
5. If you have a risk of allergy to the components of this drug.
6. If you are pregnant or possibly pregnant.
7. If you have received 23-valent pneumococcus vaccine in the past.
   (If you received pneumococcus vaccine within the past 5 years, the vaccination of this drug may aggravate the symptoms such as induration, pain, reddish discoloration, etc. of injected site.)

● Simultaneous vaccination with other vaccine(s)

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

● Precautions 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 physician.
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) ( )** **Please come to the reception around (time) on the day of vaccination.**	**Name of medical organization**	

[Reference]
When any health damage occurs due to the vaccination with pneumococcus vaccine, 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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For optional vaccination 英語

Screening questionnaire for vaccination with 23-valent pneumococcus vaccine (Pneumovax® NP)

To those who want to receive vaccination: Please fill out the answers in bold and circle all other questions (yes or no).		Body temperature before consultation	__.__ °C
Address	〒	**Phone No.**	( ) -
Kana (Japanese phonetics) Recipient's name	..... (M / F)	**Name of designated immediate contact (family member, etc.)**	
Date of birth	/ / / (d/m/y) Age at last birthday: __ years old		

Questionnaire	Answer		Physician's comment
Have you read and understood the instructions ("Those receiving 23-valent pneumococcus vaccine (Pneumovax® NP)") regarding the vaccination you will receive today?	Yes	No	
Have you received any vaccination within the past 1 month? (Type of vaccine:)	Yes	No	
Have you previously received 23-valent pneumococcus vaccine (Pneumovax® NP) or any other pneumococcal vaccine? ○ Name and date of vaccine (Vaccine Date: MM/YYYY)	Yes	No	
Do you have any unfavorable condition today? ○ Write concrete symptom. ( )	Yes	No	
Do you have any disease now? ○ Disease ( ) Are you receiving any treatment (medication, etc.) for the disease? ○ Name and type of drug ( )	Yes	No	
Have you ever undergone treatment because of a diagnosis of any disease of heart/ vessel/blood/kidney/liver/cranial nerve? ○ Disease ( )	Yes	No	
Have you had any fever or contracted any disease within the past 1 month? ○ Disease ( )	Yes	No	
Have you ever developed drug-/food- related exanthema/urticaria or showed an unfavorable condition?	Yes	No	
Have you ever developed convulsion?	Yes	No	
Have you ever become sick after vaccination? ○ Vaccination ( )	Yes	No	
Have you had your spleen removed?	Yes	No	
Do you have any questions regarding today's vaccination?	Yes	No	

Physician's comments: Based on an interview and examination, I have determined that the patient (can / should not) receive the vaccination today. The patient (or his /her designated immediate contact) has been informed of the effects and potential adverse reactions of the vaccination, and the relief provided by the Pharmaceuticals and Medical Devices Agency Act.
Physician's signature or name and seal [ ]

Consent of patient (or his/her designated immediate contact such as a family member, etc.)
I have received an examination by my physician. The vaccine has been explained to me including effects and potential adverse reactions. I understand the information provided to me. I understand the relief provided under the Pharmaceutical and Medical Device Agency Act. I agree with the above information and agree to be vaccinated. (Yes / No) Patient signature (or signature of his/her designated immediate contact such as a family member, etc.) [(Relationship of designated immediate contact to patient (if applicable):]

Vaccine name	Vaccination route	Place, physician's name, and date of vaccination
Name: Pneumovax® NP Manufacturer: MSD K.K. Lot number:	Intramuscular / Subcutaneous (dosage: 0.5 mL)	Name of hospital: Physician's name: Date of vaccination: / / / (d/m/y)

This screening questionnaire is used to improve the safety of vaccination. Personal information that you described will only be used for pre-vaccination consultation.