

# Drug Information Sheet("Kusuri-no-Shiori")

Injection

Revised: 12/2021

The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic response, patients should understand their medication and cooperate with the treatment.

**Brand name:**Prevenar13 Suspension Liquid for Injection

**Active ingredient:**Pneumococcal 13-valent conjugate vaccine

**Dosage form:**injection

**Print on wrapping:**

注射器に入っています

**Effects of this medicine**

This vaccine is made by pathogens that are neutralized pneumococci, and injection to human body causes us to create antibodies against pneumococci to help prevent infection.

It is usually used to help prevent infections in elderly adults or those\* considered at elevated risk of contracting pneumococcal diseases and invasive infections in children, both caused by Streptococcus pneumoniae serotypes of 13 kinds.

\*Those considered at elevated risk of contracting pneumococcal diseases are those with chronic heart, lung, liver or renal disease, diabetes mellitus, congenital or acquired asplenia (asplenia syndrome, those received splenectomy, etc.), sickle cell disease or other hemoglobinopathy, cochlear implant or decreased biological defense function due to anatomical factors such as chronic cerebrospinal fluid leakage, in immunodeficient state or suspected immunodeficient state due to the underlying disease or treatment, or considered as requiring vaccination by his/her doctor due to reasons other than the above.

**Before using this medicine, be sure to tell your doctor and pharmacist**

- If you have previously experienced any allergic reactions (itching, rash, etc.) to any medicines.  
If you have: fever, acute illness, a history of immunodeficiency, a family history of congenital immunodeficiency, cardiovascular disease, renal disease, liver disease, blood disease, underlying disease like on impaired development, a history of convulsion or blood coagulation disorder.  
If you have received any other vaccinations within a month.
- If you are pregnant or breastfeeding.
- If you are taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.)

**Dosing schedule (How to take this medicine)**

- Your dosing schedule prescribed by your doctor is(( to be written by a healthcare professional))
- For elderly adults or those considered at elevated risk of contracting pneumococcal diseases (prevention of pneumococcal infections): In general, administer this vaccine intramuscularly as a single dose.  
For children (prevention of invasive pneumococcal infections): In general, as initial immunization, this vaccine is injected subcutaneously 3 times at intervals of at least 27 days, and as an additional immunization, this vaccine is injected subcutaneously at least 60 days after the third administration of this vaccine.  
This vaccine is given between the age of 2 months and under the age of 6 years. Normally, the vaccination is initiated over the age of 2 months to less than 7 months, and the third immunization is completed before the age of 12 months. Additional vaccination is given between the age of 12 months and 15 months. The number of vaccination time will be decreased when you initiate an injection over the age of 7 months.
- Be sure to consult a doctor for questioning, body temperature check, etc. before the administration of this vaccine.

**Precautions while taking this medicine**

- Avoid vigorous exercise on the day of vaccination and keep the injection site clean.

**Possible adverse reactions to this medicine**

The most commonly reported adverse reactions include injection site swelling/pain, red spots in the injection site, muscle pain, fatigue, fever and somnolence (impaired consciousness due to sleepiness). If any of these symptoms occur, consult with your doctor or pharmacist.

**The symptoms described below are rarely seen as initial symptoms of the adverse reactions indicated in brackets. If any of these symptoms occur, see your doctor immediately.**

- respiratory distress, generalized hot flash, hives [shock, anaphylaxis]
- convulsion, episodic muscle twitching [convulsion]
- bruise, nose bleeding/gum bleeding, bleeding tendency [thrombocytopenic purpura]

**The above symptoms do not describe all the adverse reactions to this medicine. Consult with your**

**doctor or pharmacist if you notice any symptoms of concern other than those listed above.**

**Storage conditions and other information**

**For healthcare professional use only** / /

For further information, talk to your doctor or pharmacist.