

## ***Pneumococcal vaccine***

### **What is Pneumococcal Disease?**

Pneumococcal disease is an infection caused by the *Streptococcus pneumoniae* (*S. pneumoniae*) bacterium, also known as pneumococcus. Infection can result in pneumonia, infection of the blood (bacteremia/sepsis), middle-ear infection (otitis media), or bacterial meningitis.

The World Health Organization (WHO) says that pneumococcal disease is the world's number 1 vaccine-preventable cause of death among infants and children younger than 5 years of age.

### **There are two main types of pneumococcal diseases:**

#### **1) Non-invasive pneumococcal diseases**

These may be less serious than invasive pneumococcal disease and occur outside the major organs or the blood. *S. pneumoniae* can spread from the nasopharynx (nose and throat) to the upper and lower respiratory tract and can cause:

- ✦ Otitis media - middle ear infection. Inflammation of the middle ear, typically with accumulation of fluid in the middle ear, swelling of the eardrum, earache. If the eardrum is perforated drainage of pus into the ear canal.
- ✦ Non-bacteremic pneumonia - infection of the lower respiratory tract without detectable spread of organisms to the blood stream

#### **2) Invasive pneumococcal diseases (IPD)**

These tend to be more serious and occur inside a major organ, or in the blood. Examples of IPDs include:

- ✦ Bacteremia (sepsis) - bacterial infection of the blood. Bacteremia refers to the presence of live bacteria in the blood, while sepsis means a blood infection which is associated with capillary leak, shock and an increased risk of mortality.
- ✦ Meningitis - inflammation of the meninges. The meninges are the three membranes that cover the brain and the spinal cord.
- ✦ Bacteremic pneumonia - inflammation of one or both lungs, with pneumococcus in the bloodstream.

**How serious is pneumococcal disease?**

Pneumococcal disease ranges from mild to very dangerous. About 4,000 cases of serious disease (meningitis and sepsis) occur each year in children under 5 in the U.S. These illnesses can lead to disability like deafness, brain damage, or loss of arms or legs. About 1 out of 10 children who get pneumococcal meningitis dies.

**How dose pneumococcal disease spread?**

Pneumococcal disease spreads when an infected person sneezes or coughs.

Children can carry the bacteria in their nose and throat, and spread the bacteria, without being sick. Sometimes the bacteria spread from the nose and throat into the blood or lungs, causing severe disease. Other times it can spread to ears or sinuses, causing mild infections

***Two vaccines available in King Abdullah University Hospital against pneumococcal disease there are :***

- ✦ Prevenar 13
- ✦ PNEUMOVAX® 23



## Prevenar 13

### What is a prevenar 13?

It is a pneumococcal vaccine, which is given to children from 6 weeks to 5 years to help protect against disease caused by 13 types of the bacteria *Streptococcus pneumoniae* such as:

- Meningitis
- Sepsis or bacteraemia
- Pneumonia
- Ear infection ( otitis media )

The vaccine works by provoking the body's immune response to the bacteria, without causing the diseases.

### What is a prevenar 13 used for?

- Ⓢ **Children 6 weeks through 5 years of age** , indication for
  - ✗ Active immunization for the prevention of invasive disease caused by *Streptococcus pneumoniae* serotypes 1 , 3 , 4 , 5 , 6A , 6B , 7F , 9V , 14 , 18C , 19A , 19F and 23F.
  - ✗ Active immunization for the prevention of otitis media caused by *Streptococcus pneumoniae* serotypes 4 , 6B , 9V , 14 , 18C , 19F and 23F .
- Ⓢ **Children 6 years through 17 years of age** , indication for :
  - ✗ Active immunization for the prevention of invasive disease caused by *Streptococcus pneumoniae* serotypes 1 , 3 , 4 , 5 , 6A , 6B , 7F , 9V , 14 , 18C , 19A , 19F and 23F.

Ⓢ **Adult 50 years of age and older** , indication for :

✗ Active immunization for the prevention of invasive disease caused by Streptococcus pneumonia serotypes 1 , 3 , 4 , 5 , 6A , 6B , 7F , 9V , 14 , 18C , 19A , 19F and 23F. This indication is based on immune responses elicited by prevar 13.

Ⓢ **Limitation of prevar 13 use and effectiveness :**

✗ Prevar 13 does not protect against disease caused by S. Pneumonia serotypes that are not in the vaccine.

✗ The effectiveness of prevar 13 administered less than 5 years after Pneumovax®23 is not known.

**Dosage form, strengths and which site in body are it given?**

Prevar 13 is a suspension for intramuscular injection available 0.5 ml single- dose prefilled syringes.

Injected to anterolateral aspect of thigh in infant and deltoid muscle of the upper arm in toddlers, children and adult

**Vaccination schedule**

**1. Infants and Toddlers**

Age at Dose	2 months	4 months	6 months	12-15 months
Dose	First dose	Second dose	Third dose	Fourth dose

**2. Unvaccinated children 7 months through 5 years of age**

Age at first dose	Total number of 0.5 ml doses
7-11 months	3
12-23 months of age	2
24 months through 5 years of age (prior to the 6 <sup>th</sup> birth )	1

**3. Children previously vaccinated with prevnar pneumococcal 7-valent conjugate vaccine (Diphtheria CRM<sub>197</sub> protein)**

Children 15 months through 5 years of age who are considered completely immunized with prevnar may receive one dose of prevnar 13 to elicit immune responses to the six additional serotypes.

This supplemental dose of prevnar 13 should be administered with an interval of at least 8 weeks after the final dose of prevnar.

**4. Children 6 years through 17 years age**

Prevnar is administered as single dose. If prevnar was previously administered then at least 8 weeks should elapse before receiving prevnar 13

**5. Adult 50 years of age and older**

Prevnar is administered as single dose.

**Not to be used in:**

- ✘ People with a fever or sudden severe illness (in this case the vaccine should be postponed until after recovery).
- ✘ People with known sensitivity or allergy to diphtheria toxoid:
  - If you or your child are allergic to any of its ingredients. Please inform your doctor or pharmacist.
  - If you feel your child has experienced an allergic reaction after having this vaccine, inform your doctor or pharmacist immediately.

**Used with caution in**

- ✗ Children with a personal or family history of febrile convulsions.
  - These children can still be given this vaccine, but it may be recommended that you give them a dose of paracetamol or ibuprofen (e.g. Nurofen for children) to prevent the child getting a fever after having this vaccine.
- ✗ People at risk of bleeding following an injection into muscle, e.g. children with haemophilia or thrombocytopenia. The injection should be given under the skin rather than into a muscle in these people.

**Special population**

**Pregnancy**

Pneumococcal 13-valent vaccine has been assigned to pregnancy category C by the FDA. Animal studies have not been reported. There are no controlled data in human pregnancy. Pneumococcal vaccine is not approved for use after the 6th birthday.

**Breastfeeding**

There are no data on the excretion of pneumococcal 13-valent vaccine into human milk. Pneumococcal 13-valent vaccine is not approved for use after the 6th birthday.

**Side effects**

- ✗ Pain, tenderness, swelling, redness or hardening of the skin at the injection site.
- ✗ Fever
- ✗ Irritability
- ✗ Drowsiness
- ✗ Restless sleep
- ✗ Decreased appetite

**What other drugs will affect Prevnar 13?**

Before receiving Prevnar 13, tell the doctor about all other vaccines you or your child have recently received.

Also tell the doctor if you or your child has recently received drugs or treatments that can weaken the immune system, including:

- ✗ an oral, nasal, inhaled, or injectable steroid medicine;
- ✗ chemotherapy or radiation;
- ✗ medications to treat psoriasis, rheumatoid arthritis, or other autoimmune disorders, such as azathioprine (Imuran), etanercept (Enbrel), leflunomide (Arava), and others; or
- ✗ medicines to treat or prevent organ transplant rejection, such as basiliximab (Simulect), cyclosporine (Sandimmune, Neoral, Gengraf), muromonab CD3 (Orthoclone), mycophenolate mofetil (CellCept), sirolimus (Rapamune), or tacrolimus (Prograf).

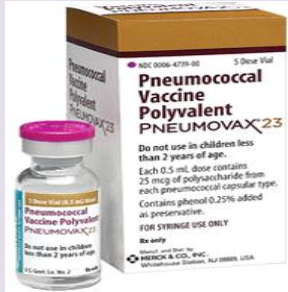
If you are using any of these medications, you may not be able to receive the vaccine, or may need to wait until the other treatments are finished.

**Storage Condition**

Store in a refrigerator (2°C–8°C).

Do not freeze.

Prevnar 13 is stable at temperatures up to 25°C for four days. At the end of this period Prevnar 13 should be used or discarded. These data are intended to guide health care professionals in case of temporary temperature excursions.



## PNEUMOVAX® 23

### What is Pneumovax 23 ?

PNEUMOVAX 23 is a vaccine indicated for active immunization for the prevention of pneumococcal disease caused by the 23 serotypes contained in the vaccine (1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19F, 19A, 20, 22F, 23F, and 33F)

### Who should be vaccinated?

individuals at risk (those with heart disease, lung disease, liver or kidney disease, diabetes, alcoholism, no spleen, sickle cell anemia, or HIV/AIDS, or those living in a nursing home, or for people living in communities where pneumococcal infection spreading quickly)

### What is a Pneumovax 23 used for?

PNEUMOVAX 23 is approved for use in persons 50 years of age or older and persons aged  $\geq 2$  years who are at increased risk for pneumococcal disease protect against serious infection ( e.g. meningitis , bacteria in the blood ) due to certain bacteria ( Streptococcus pneumonia ).

This vaccine is important for preventing infection in individuals at risk (e.g., those with heart disease, lung disease, liver disease, diabetes, alcoholism, spleen problems, sickle cell anemia, or HIV or those living in a nursing home)

### Mechanism of Action

PNEUMOVAX 23 induces type-specific antibodies that enhance opsonization, phagocytosis, and killing of pneumococci by leukocytes and other phagocytic cells.



**DOSAGE AND ADMINISTRATION**

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. If either of these two conditions exists, the vaccine should not be administered

Use a separate sterile syringe and needle for each individual patient to prevent transmission of infectious agents from one person to another .

Withdraw 0.5 mL from the vial using a sterile needle and syringe free of preservatives, antiseptics, and detergents

Administer a single 0.5-mL dose of PNEUMOVAX 23 intramuscularly or subcutaneously into the deltoid muscle or lateral mid-thigh

**WARNINGS AND PRECAUTIONS**

- ✗ Persons with Moderate or Severe Acute Illness
- ✗ Persons with Severely Compromised Cardiovascular or Pulmonary Function
- ✗ Use of Antibiotic Prophylaxis
- ✗ Persons with Altered Immunocompetence
- ✗ Persons with Chronic Cerebrospinal Fluid Leakage
- ✗ Person have been vaccinated with pneumococcal vaccine before
- ✗ Person with allergy to any other medicine or vaccine or any other substance such as food, preservative or dyes

**Who should not get PNEUMOVAX 23 ?**

- ✗ are allergic to any of its ingredients
- ✗ had an allergic reaction to PNEUMOVAX 23 in the past
- ✗ are less than 2 years old

**What should I tell my health care provider before getting PNEUMOVAX 23 ?**

- ✗ are allergic to PNEUMOVAX 23
- ✗ have heart or lung problems
- ✗ have a fever
- ✗ have immune problems or are receiving radiation treatment for chemotherapy
- ✗ are pregnant or breast-feeding

**ADVERSE REACTIONS**

**General disorders and administration site conditions**

Cellulitis, Malaise, Fever ,Warmth at the injection site, Decreased limb mobility,Peripheral edema in the injected extremity

**Digestive system** :nausea, vomiting

**Hematologic/Lymphatic** :Lymphadenitis, Lymphadenopathy , Thrombocytopenia in patients with stabilized idiopathic thrombocytopenic purpura<sup>3</sup>, Hemolytic anemia in patients who have had other hematologic disorders , Leukocytosis.

**Hypersensitivity reactions including** :Anaphylactoid reactions, Serum Sickness, Angioneurotic edema

**Musculoskeletal System** : Arthralgia, Arthritis

**Nervous System** : Paresthesia, Radiculoneuropathy, Guillain-Barré syndrome, Febrile, convulsion

**Skin** :Rash, Urticaria ,Cellulitis-like reactions, Erythema multiforme

## **DRUG INTERACTIONS**

In a randomized clinical study, a reduced immune response to ZOSTAVAX® as measured by gpELISA was observed in individuals who received concurrent administration of PNEUMOVAX 23 and ZOSTAVAX compared with individuals who received these vaccines 4 weeks apart. Consider administration of the two vaccines separated by at least 4 weeks

PNEUMOVAX 23 May not work as well as it should if you taking medicines that decrease the immune system so your doctor will decide whether or not to give the vaccine

## **USE IN SPECIFIC POPULATIONS**

### **Pregnancy**

Pregnancy Category C: Animal reproduction studies have not been conducted with PNEUMOVAX 23

It is also not known whether PNEUMOVAX 23 can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. PNEUMOVAX 23 should be given to a pregnant woman only if clearly needed

### **Nursing Mothers**

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when PNEUMOVAX 23 is to a nursing woman

### **Pediatric Use**

PNEUMOVAX 23 is not approved for use in children less than 2 years of age. Children in this age group do not develop an effective immune response to the capsular types contained in this polysaccharide vaccine

### **Immunocompromised Individuals**

Persons, who are immunocompromised, including persons receiving immunosuppressive therapy, may have a diminished immune response to PNEUMOVAX 23

### **Geriatric**

Individual 65 years and older may not tolerate medical interventions as well as younger individual. A higher frequency and/or a greater severity of reactions in some older individuals cannot be ruled out.

## *Drug Information Center/KAUH*

Post-marketing reports have been received in which some elderly individuals had severe adverse experiences and a complicated clinical course following vaccination .

Some individuals with underlying medical conditions of varying severity experienced local reactions and fever associated with clinical deterioration requiring hospital care

### **Storage and Handling**

Store unopened and opened vials at 2-8°C (36-46°F)

All vaccine must be discarded after the expiration date

### References:

- 1- Drugs leaflets.
- 2- Daniel M Musher. Pneumococcal vaccination in adults and children. Nov 19, 2013. <http://www.uptodate.com/contents/pneumococcal-vaccination-in-adults>.

*THE END ....*



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