

PNEUMO 23

Polysaccharide polyvalent pneumococcal vaccine

NAME OF MEDICINE

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PRESENTATION

PNEUMO 23 is a clear colourless solution for injection by intramuscular (i.m.) or subcutaneous (s.c.) route. Each single dose syringe (0.5mL) contains 25 micrograms of *Streptococcus pneumoniae*, purified polysaccharides of each of the following 23 types: 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F, 33F.

Each 0.5mL dose also contains phenol ≤ 1.25 mg as a preservative in a phenol buffered solution of sodium chloride, disodium phosphate, monosodium phosphate and water for injections.

The vaccine should be used directly as supplied; no dilution or reconstitution is necessary.

USES

ACTIONS

The vaccine is prepared from purified pneumococcal capsular polysaccharide antigens derived from the 23 serotypes that account for approximately 90% of invasive pneumococcal disease types. The vaccine induces type-specific humoral antibodies which are effective in preventing pneumococcal disease. In clinical trials, the immunogenicity of each of the 23 capsular types has been demonstrated when tested in polyvalent vaccines.

The conferred immunity appears from 2 to 3 weeks after immunisation and lasts about 5 years.

PHARMACOKINETICS

Not relevant for vaccines.

INDICATIONS

Pneumo 23 is indicated for high risk subjects ≥ 2 years of age to prevent pneumococcal pneumonia and systemic pneumococcal infections caused by the serotypes included in the vaccine.

Groups identified at increased risk:

Elderly people from 65 years of age

Immunocompetent patients with chronic illness (eg. cardiovascular disease, pulmonary disease, diabetes mellitus, alcoholism, cirrhosis, cerebrospinal fluid leaks).

Immunocompromised patients: anatomic or functional asplenia (including patients to be splenectomized), sickle cell disease, Hodgkins disease, lymphoma, multiple myeloma, chronic renal failure, nephrotic syndrome and organ transplantation.

Asymptomatic or symptomatic HIV infected patients.

Special groups: persons living in a social or working environment with an identified increased risk of pneumococcal infection or its complications (eg. hospitalized elderly people or those in institutional care).

Children under 2 years of age: the vaccine is not recommended because antibody responses may be poor in this age group. Also, the safety and efficacy of pneumococcal vaccines have not been established in children under 2 years of age. It should be noted that recurrent upper respiratory tract infections, particularly otitis media and sinusitis, are not an indication for this vaccination.

DOSAGE AND ADMINISTRATION

Primary immunisation consists of a single 0.5mL dose. Intramuscular administration (i.m.) is preferred, although subcutaneous injection (s.c.) can be used.

Reimmunisation consists of a single 0.5 mL dose, administered by intramuscular or subcutaneous injection. Given the current state of knowledge, systemic reimmunisation of all subjects previously given pneumococcal vaccine is not necessary. It is however recommended for subjects at high risk of pneumococcal infection (eg. people with asplenia), who were given pneumococcal vaccine more than 5 years ago, or whose antibody titre has been declining sharply (eg. nephrotic syndrome, renal failure or people with organ transplant). A reimmunisation every 3 or 5 years is also recommended for children under 10 years of age with nephrotic syndrome, asplenia or sickle cell disease.

CONTRAINDICATIONS

- Hypersensitivity to any component of the vaccine.
- Usual contraindications to any immunisation: immunisation should be delayed in case of significant febrile illness, acute disease, relapse of chronic disease, unless a lethal risk exists (see Indications).
- Immunization is not recommended in subjects who were given a pneumococcal vaccine within the previous three years, except in specific indications (see Dosage and Administration).
- A confirmed or suspected episode of pneumococcal infection is not a contraindication and should be considered according to underlying risk status (see Adverse Effects).

WARNINGS AND PRECAUTIONS

Do not inject vaccine intradermally.

PNEUMO 23 should never be injected intravascularly and precautions should be taken to make sure the needle does not enter a blood vessel.

The possibility of severe reactions (of the Arthus phenomenon type) occurring during reimmunization calls for:

- strict respect for the contraindications,
- thorough assessment of the theoretical advantages, taking into account the fact that efficacy of this immunization has been established only for specific high-risk groups.

It is recommended that pneumococcal vaccine be given at least two weeks before a splenectomy, the initiation of chemotherapy or of an immunosuppressive treatment. Required prophylactic antibiotic therapy against pneumococcal infection should not be stopped after immunization with the vaccine.

Use in Pregnancy

No animal reproductive studies have been carried out with Pneumo 23. No teratogenic effects have been reported during its clinical use in humans. The vaccine is not recommended during the first trimester of pregnancy. A clinical trial was performed with PNEUMO 23 in pregnant women during the third trimester. No significant adverse events were recorded.

Breast feeding is not a contra-indication to pneumococcal vaccination. PNEUMO 23 may be given to lactating women.

ADVERSE EFFECTS

- Local reactions at the injection site: pain, erythema, induration and oedema are the more commonly reported reactions. These reactions are generally mild and transient.
- Very rare Arthus-like reactions have been reported. They are reversible without after-effects and mainly occur in persons with high initial pneumococcal antibody levels.
- Systemic reactions: a moderate and transient fever ($>38^{\circ}\text{C}$) is observed in about 2% of patients. Fever ($> 39^{\circ}\text{C}$) may rarely be observed. Febrile episodes mostly occur very early after vaccination. They are self-resolving within 24 hours.

Other general reactions such as lymphadenopathy, rash, urticaria, arthralgia, anaphylactoid reactions, headache, myalgia, malaise, asthenia and fatigue have been exceptionally reported.

INTERACTIONS

PNEUMO 23[®] may be simultaneously administered with other vaccines at different injection sites (particularly with influenza vaccine and those used for routine childhood immunisation).

The expected serum antibody response may not be obtained in patients receiving immunosuppressive therapy.

The vaccine should not be mixed with any other medicine prior to administration.

OVERDOSAGE

There are no reports of overdosage.

PHARMACEUTICAL PRECAUTIONS

Store at $2-8^{\circ}\text{C}$. Do not freeze.

Shelf-Life: 2 Years

MEDICINE CLASSIFICATION

Prescription Medicine

PACKAGE QUANTITIES

1 single dose prefilled syringe (0.5 mL)

FURTHER INFORMATION

Nil

PNEUMO 23 DATA SHEET

MANUFACTURER

Sanofi Pasteur SA
Lyon, France

DISTRIBUTOR

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1 November 2007