PNEUMOVAX 23
(pneumococcal vaccine polyvalent)
Injection

PNEUMOVAX 23 (pneumococcal vaccine polyvalent), is a sterile, liquid vaccine for intramuscular or subcutaneous injection. It consists of a mixture of highly purified capsular polysaccharides from the 23 most prevalent or invasive pneumococcal types of Streptococcus pneumoniae, including the six serotypes that most frequently cause invasive drug-resistant pneumococcal infections among adults in the United States (see Table 1). The 23-valent vaccine accounts for at least 90% of pneumococcal blood isolates and at least 85% of all pneumococcal isolates from sites which are generally sterile as determined by ongoing surveillance of United States data.

PNEUMOVAX 23 is manufactured according to methods developed by the MERCK RESEARCH LABORATORIES. Each 0.5 mL dose of vaccine contains 25 mcg of each polysaccharide type dissolved in isotonic saline solution containing 0.25% phenol as a preservative.

Table 1
23 Pneumococcal Capsular Types Included in PNEUMOVAX 23

Danish Nomenclature	Pneumococcal Types
1	1
2	2
3	3
4	4
5	5
6B**	6B**
7F	7F
8	8
9N	9N
9V**	9V**
10A	10A
11A	11A
12F	12F
14**	14**
15B	15B
17F	17F
18C	18C
19A**	19A**
19F**	19F**
20	20
22F	22F
23F**	23F**
33F	33F

**These serotypes most frequently cause drug-resistant pneumococcal infections

CLINICAL PHARMACOLOGY

Pneumococcal infection is a major cause of pneumonia, bacteremia, meningitis, and otitis media. Strains of drug-resistant S. pneumoniae have become increasingly common in the United States and in other parts of the world. In some areas as many as 35% of pneumococcal isolates have been reported to be resistant to penicillin. Many penicillin resistant pneumococci are also resistant to other antimicrobial drugs (e.g., erythromycin, trimethoprimsulfamethoxazole and extended-spectrum cephalosporins), therefore emphasizing the importance of vaccine prophylaxis against pneumococcal disease.

Epidemiology

Pneumococcal infection causes approximately 40,000 deaths annually in the United States. At least 500,000 cases of pneumococcal pneumonia are estimated to occur annually in the United States; S. pneumoniae accounts for approximately 25%-35% of cases of community-acquired bacterial pneumonia in persons who require hospitalization.

Pneumococcal disease accounts for an estimated 50,000 cases of pneumococcal bacteremia annually in the United States. Some studies suggest the overall annual incidence of bacteremia to be approximately 15 to 30 cases/100,000 population with 50 to 83 cases/100,000 for persons 65 years of age and older.

The incidence of pneumococcal bacteremia is as high as 1% (940 cases/100,000 population) among persons with acquired immunodeficiency syndrome (AIDS).

In the United States, the risk of acquiring bacteremia is lower among whites than among persons in other racial/ethnic groups (i.e., Blacks, Alaskan Natives, and American Indians).

Despite appropriate antimicrobial therapy and intensive medical care, the overall case-fatality rate for pneumococcal bacteremia is 15%-20% among adults, and among elderly patients this rate is approximately 30%-40%. An overall case-fatality rate of 36% was documented for adult inner-city residents who were hospitalized for pneumococcal bacteremia.

In the United States, pneumococcal disease accounts for an estimated 3,000 cases of meningitis annually. The estimated overall annual incidence of pneumococcal meningitis is approximately 1 to 2 cases per 100,000 population.

In adults, the incidence of pneumococcal meningitis is highest among persons aged ≥ 65 years.

Recurrent pneumococcal meningitis may occur in patients who have chronic cerebrospinal fluid leakage resulting from congenital lesions, skull fractures, or neurosurgical procedures.

Invasive pneumococcal disease (e.g., bacteremia or meningitis) and pneumonia cause high morbidity and mortality in spite of effective antimicrobial control by antibiotics. These effects of pneumococcal disease appear due to irreversible physiologic damage caused by the bacteria during the first 5 days following onset of illness and occur irrespective of antimicrobial therapy. Vaccination offers an effective means of further reducing the mortality and morbidity of this disease.

Risk Factors

In addition to persons 65 years of age or older, patients with certain chronic conditions are at increased risk of developing pneumococcal infection and severe pneumococcal illness.

Patients with chronic cardiovascular diseases (e.g., congestive heart failure or cardiomyopathy), chronic pulmonary diseases (e.g., chronic obstructive pulmonary disease or emphysema), or chronic liver diseases (e.g., cirrhosis), diabetes mellitus, alcoholism or asthma (when it occurs with chronic bronchitis, emphysema, or long-term use of systemic corticosteroids) have an increased risk of pneumococcal disease. In adults, this population is generally immunocompetent.

Patients at high risk are those who have a decreased responsiveness to polysaccharide antigen or an increased rate of decline in serum antibody concentrations as a result of: immunosuppressive conditions (congenital immunodeficiency, human immunodeficiency virus [HIV] infection, leukemia, lymphoma, multiple myeloma, Hodgkins disease, or generalized malignancy); organ or bone marrow transplantation; therapy with alkylating agents, antimetabolites, or systemic corticosteroids; chronic renal failure or nephrotic syndrome.

Patients at the highest risk of pneumococcal infection are those with functional or anatomic asplenia (e.g., sickle cell disease or splenectomy), because this condition leads to reduced clearance of encapsulated bacteria from the bloodstream.

Immunogenicity

It has been established that the purified pneumococcal capsular polysaccharides induce antibody production and that such antibody is effective in preventing pneumococcal disease. Clinical studies have demonstrated the immunogenicity of each of the 23 capsular types when tested in polyvalent vaccines.

Studies with 12-, 14-, and 23-valent pneumococcal vaccines in adults of all ages showed immunogenic responses.

Protective capsular type-specific antibody levels generally develop by the third week following vaccination.

Bacterial capsular polysaccharides induce antibodies primarily by T-cell-independent mechanisms.

Immunogenicity following concomitant administration

In a double-blind, controlled clinical trial, 473 adults, 60 years of age or older, were randomized to receive ZOSTAVAX and PNEUMOVAX 23 concomitantly (N=237), or PNEUMOVAX 23 alone followed 4 weeks later by ZOSTAVAX alone (N=236). At

four weeks postvaccination, the VZV antibody levels following concomitant use were significantly lower than the VZV antibody levels following nonconcomitant administration (GMTs of 338 vs. 484 gpELISA units/mL, respectively; GMT ratio = 0.70 (95% CI: [0.61, 0.80])). VZV antibody levels 4 weeks postvaccination were increased 1.9-fold (95% CI: [1.7, 2.1]; meeting the pre-specified acceptance criterion) in the concomitant group vs. 3.1-fold (95% CI: [2.8, 3.5]) in the nonconcomitant group. The GMTs for PNEUMOVAX 23 antigens were comparable between the two groups. Concomitant use of ZOSTAVAX and PNEUMOVAX 23 demonstrated a safety profile that was generally similar to that of the two vaccines administered nonconcomitantly.

Efficacy

A prospective study in France found pneumococcal vaccine to be 77% effective in reducing the incidence of pneumonia among nursing home residents.

In the United States, two postlicensure randomized controlled trials, in the elderly or patients with chronic medical conditions who received a multivalent polysaccharide vaccine, did not support the efficacy of the vaccine for nonbacteremic pneumonia. However, these studies may have lacked sufficient statistical power to detect a difference in the incidence of laboratory-confirmed, nonbacteremic pneumococcal pneumonia between the vaccinated and nonvaccinated study groups.

A meta-analysis of nine randomized controlled trials of pneumococcal vaccine concluded that pneumococcal vaccine is efficacious in reducing the frequency of nonbacteremic pneumococcal pneumonia among adults in low-risk groups but not in high-risk groups. These studies may have been limited because of the lack of specific and sensitive diagnostic tests for nonbacteremic pneumococcal pneumonia.

More recently, multiple case-control studies have shown pneumococcal vaccine is effective in the prevention of serious pneumococcal disease, with point estimates of efficacy ranging from 56% to 81% in immunocompetent persons.

Only one case-control study did not document effectiveness against bacteremic disease possibly due to study limitations, including small sample size and incomplete ascertainment of vaccination status in patients. In addition, case-patients and persons who served as controls may not have been comparable

regarding the severity of their underlying medical conditions, potentially creating a biased underestimate of vaccine effectiveness.

A serotype prevalence study, based on the Centers for Disease Control pneumococcal surveillance system, demonstrated 57% overall protective effectiveness against invasive infections caused by serotypes included in the vaccine in persons ≥ 6 years of age, 65-84% effectiveness among specific patient groups (e.g., persons with diabetes mellitus, coronary vascular disease, congestive heart failure, chronic pulmonary disease, and anatomic asplenia) and 75% effectiveness in immunocompetent persons aged ≥ 65 years of age. Vaccine effectiveness could not be confirmed for certain groups of immunocompromised patients; however, the study could not recruit sufficient numbers of unvaccinated patients from each disease group.

Duration of Immunity

Following pneumococcal vaccination, serotype-specific antibody levels decline after 5-10 years. A more rapid decline in antibody levels may occur in some groups. Limited published data suggest that antibody levels may decline rapidly in the elderly > 65 years of age. These findings indicate that revaccination may be needed to provide continued protection (See INDICATIONS AND USAGE, Revaccination.)

INDICATIONS AND USAGE

PNEUMOVAX 23 is indicated for vaccination against pneumococcal disease caused by 23 pneumococcal serotypes covered by Pneumovax 23.

Vaccination with PNEUMOVAX 23 is recommended for persons 50 years of age or older.

POSOLOGY

Administer a single 0.5-mL dose of PNEUMOVAX 23 subcutaneously or intramuscularly (preferably in the deltoid muscle or lateral mid-thigh), with appropriate precautions to avoid intravascular administration.

Timing of Vaccination

Pneumococcal vaccine should be given at least two weeks before elective splenectomy, if possible. For planning cancer chemotherapy or other immunosuppressive therapy (e.g., for patients with Hodgkin's disease or those who undergo organ or bone marrow transplantation), the interval between vaccination and initiation of immunosuppressive therapy should be at least two weeks. Vaccination during chemotherapy or radiation therapy should be avoided. Pneumococcal vaccine may be given several months following completion of chemotherapy or radiation therapy for neoplastic disease. In Hodgkin's disease, immune response to vaccination may be suboptimal for two years or longer after intensive chemotherapy (with or without radiation). For some patients, during the two years following the completion of chemotherapy or other immunosuppressive therapy (with or without radiation), significant improvement in antibody response has been observed, particularly as the interval between the end of treatment and pneumococcal vaccination increased.

Persons with asymptomatic or symptomatic HIV infection should be vaccinated as soon as possible after their diagnosis is confirmed.

Revaccination

All persons ≥ 65 years of age who have not received vaccine within 5 years (and were < 65 years of age at the time of vaccination) should receive another dose of vaccine.

Because data are insufficient concerning the safety of pneumococcal vaccine when administered three or more times, revaccination following a second dose is not routinely recommended.

Do not inject intravenously or intradermally.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. PNEUMOVAX 23 is a clear, colorless solution. The prefilled syringe is for single use only. Inject the entire contents of the syringe. It is important to use a separate sterile syringe and needle for each individual patient to prevent transmission of infectious agents from one person to another.

Use With Other Vaccines

It is recommended that pneumococcal vaccine may be administered at the same time as influenza vaccine (by separate injection in the other arm) without an increase in side effects or decreased antibody response to either vaccine. In contrast to pneumococcal vaccine, influenza vaccine is recommended annually, for appropriate populations.

PNEUMOVAX 23 and ZOSTAVAX* should not be given concurrently because concomitant use in a clinical trial resulted in reduced immunogenicity of ZOSTAVAX. In this trial, the immunogenicity of PNEUMOVAX 23 was not affected by ZOSTAVAX.
Consider administration of the two vaccines separated by at least 4 weeks.

CONTRAINDICATIONS

Hypersensitivity to any component of the vaccine. Epinephrine injection (1:1000) must be immediately available should an acute anaphylactoid reaction occur due to any component of the vaccine.

PRECAUTIONS

General

If the vaccine is used in persons receiving immunosuppressive therapy, the expected serum antibody response may not be obtained and potential impairment of future immune responses to pneumococcal antigens may occur. (See INDICATIONS AND USAGE, Timing of Vaccination.)
Intradermal administration may cause severe local reactions.

Caution and appropriate care should be exercised in administering PNEUMOVAX 23 to individuals with severely compromised cardiovascular and/or pulmonary function in whom a systemic reaction would pose a significant risk.
Any febrile respiratory illness or other active infection is reason for delaying use of PNEUMOVAX 23, except when, in the opinion of the physician, withholding the agent entails even greater risk.
In patients who require penicillin (or other antibiotic) prophylaxis against pneumococcal infection, such prophylaxis should not be discontinued after vaccination with PNEUMOVAX 23.

As with any vaccine, vaccination with PNEUMOVAX 23 may not result in complete protection in all recipients.

Pregnancy

It is not known whether PNEUMOVAX 23 can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity.

Nursing Mothers

It is not known whether this vaccine is excreted in human milk.

Elderly

Persons 65 years of age or older were enrolled in several clinical studies of PNEUMOVAX 23 that were conducted pre- and post-licensure. In the largest of these studies, the safety of PNEUMOVAX 23 in adults 65 years of age and older (n=629) was compared to the safety of PNEUMOVAX 23 in adults 50 to 64 years of age (n=379). The subjects in this study were ambulatory and had an expected prevalence of age associated chronic diseases. The clinical data did not suggest an increased rate or severity of adverse reactions among subjects ≥ 65 years of age compared to those 50 to 64 years of age. However, since elderly individuals may not tolerate medical interventions as well as younger individuals, a higher frequency and/or a greater severity of reactions in some older individuals cannot be ruled out. Postmarketing reports have been received in which some frail elderly individuals with multiple co-morbid conditions had severe adverse experiences and a complicated clinical course following vaccination.

SIDE EFFECTS

The following adverse experiences have been reported with PNEUMOVAX 23 in clinical trials and/or post-marketing experience: Injection site reactions, consisting of pain, soreness, erythema, warmth, swelling, local induration, decreased limb mobility and peripheral edema in the injected extremity. Rarely, cellulitis-like reactions were reported. These cellulitis-like reactions, reported in postmarketing experience, show short onset time from vaccine administration. Local reactions may be accompanied by

systemic signs and symptoms including fever, leukocytosis and an increase in the laboratory value for serum C-reactive protein.

The most common adverse experiences reported in clinical trials were fever (≤ 38.8°C/102°F), injection site reactions including soreness, erythema, warmth, swelling and local induration.

In a randomized, double-blind, placebo-controlled crossover clinical trial, subjects were enrolled in four different cohorts defined by age (50-64 years of age and ≥65 years of age) and vaccination status (no pneumococcal vaccination or receipt of a pneumococcal polysaccharide vaccine 3-5 years prior to the study). Subjects in each cohort were randomized to receive intramuscular injections of PNEUMOVAX 23 followed by placebo (saline containing 0.25% phenol), or placebo followed by PNEUMOVAX 23, at 30day (±7 days) intervals. The safety of an initial vaccination (first dose) was compared to revaccination (second dose) with PNEUMOVAX 23 for 14 days following each vaccination.

Table 1 presents the adverse event rates for all solicited and unsolicited reactions reported in ≥1% in any group in this study, without regard to causality.

Table 1: Incidence of Injection-Site and Systemic Complaints in Adults ≥50 Years of Age Receiving Their First (Initial) or Second (Revaccination) Dose of PNEUMOVAX 23 (Pneumococcal Polysaccharide Vaccine, 23 Valent) or Placebo Occurring at ≥1% in Any Group

	PNEUMOVAX 23 **Initial Vaccination** **N=444**	**PNEUMOVAX 23** **Revaccination*** **N=564**	**Placebo Injection†** **N=1008**
Number Followed for Safety	438	548	984‡
	AE Rate	AE Rate	AE Rate
Injection-Site Complaints			
Solicited Events			
Pain/Soreness/Tenderness	60.0%	77.2%	7.7%

Swelling/Induration	20.3%	39.8%	2.8%
Erythema	16.4%	34.5%	3.3%
Unsolicited Events			
Ecchymosis	0%	1.1%	0.3%
Pruritus	0.2%	1.6%	0.0%
Systemic Complaints			
Solicited Events			
Asthenia/Fatigue	13.2%	17.9%	6.7%
Chills	2.7%	7.8%	1.8%
Myalgia	11.9%	17.3%	3.3%
Headache	17.6%	18.1%	8.9%
Unsolicited Events			
Fever[§]	1.4%	2.0%	0.7%
Diarrhea	1.1%	0.7%	0.5%
Dyspepsia	1.1%	1.1%	0.9%
Nausea	1.8%	1.8%	0.9%
Back Pain	0.9%	0.9%	1.0%
Neck Pain	0.7%	1.5%	0.2%
Upper Respiratory Infection	1.8%	2.6%	1.8%
Pharyngitis	1.1%	0.4%	1.3%

*Subjects receiving their second dose of pneumococcal polysaccharide vaccine as PNEUMOVAX 23 approximately 3-5 years after their first dose.

[†]Subjects receiving placebo injection from this study combined over periods.

[‡]The number of subjects receiving placebo followed for injection-site complaints. The corresponding number of subjects followed for systemic complaints was 981.

[§] Fever events include subjects who felt feverish in addition to subjects with elevated temperature.

In this clinical trial, an increased rate of self-limited local reactions has been observed with revaccination at 3-5 years following primary vaccination. It was reported that the overall injection-site adverse experiences rate for subjects ≥ 65 years of age was higher following revaccination (79.3%) than following primary vaccination (52.9%). The reported overall injection-site adverse experiences rate for re-vaccinees and primary vaccinees who were 50 to 64 years of age were similar (79.6% and 72.8% respectively). In both age groups, re-vaccinees reported a higher rate of a composite endpoint (any of the following: moderate pain, severe pain, and/or large induration at the injection site) than primary vaccinees. Among subjects ≥ 65 years of age, the composite endpoint was reported by 30.6% and 10.4 % of revaccination and primary vaccination subjects, respectively, while among subjects 50-64 years of age, the endpoint was reported by 35.5% and 18.9% respectively. The injection site reactions occurred within the 3 day monitoring period and typically resolved by day 5. The rate of overall systemic adverse experiences was similar among both primary vaccinees and re-vaccinees within each age group. The most common systemic adverse experiences were as follows: asthenia/fatigue, myalgia and headache. The observed generally small increase (≤ 13%) in post-vaccination use of analgesics returned to baseline by day 5.
Other adverse experiences reported in clinical trials and/or in post-marketing experience include:

Body as a whole
Cellulitis
Asthenia
Fever
Chills
Malaise

Digestive System
Nausea
Vomiting

Hematologic/Lymphatic System
Lymphadenitis

Lymphadenopathy
Thrombocytopenia in patients with stabilized idiopathic thrombocytopenic purpura
Hemolytic anemia in patients who have had other hematologic disorders
Leukocytosis

Hypersensitivity reactions including:
Anaphylactoid reactions
Serum sickness
Angioneurotic edema

Musculoskeletal System
Arthralgia
Arthritis
Myalgia

Nervous System
Headache
Paresthesia
Radiculoneuropathy
Guillain-Barre syndrome
Febrile convulsion

Skin
Rash
Urticaria
Erythema multiforme

STORAGE CONDITION

Store at 2-8° C (35.6-46.4° F). The vaccine is used directly as supplied. No dilution or reconstitution is necessary. Phenol 0.25% added as preservative. All vaccine must be discarded after the expiration date.

HARUS DENGAN RESEP DOKTER

Manufactured by:
Merck Sharp & Dohme Corp.,
West Point, PA 19486, USA

Released by:
Merck Sharp & Dohme B.V.
Haarlem, Netherlands

Registered by:
PT Merck Sharp Dohme Pharma Tbk
Pasuruan, Jawa Timur

Box, 1 syringe @ 0,5 mL – Reg No. DKIXXXXXXXXXX
Box, 10 syringe @ 0,5 mL – Reg No. DKIXXXXXXXXXX

Informasi untuk Pasien tentang Pneumovax 23
(vaksin pneumokokus polivalen)

Apa Pneumovax 23?

Pneumovax 23 (vaksin pneumokokus, polivalen) adalah vaksin injeksi untuk membantu mencegah infeksi, seperti pneumonia dan bakteremia (infeksi berat dalam darah) , yang disebabkan oleh beberapa jenis bakteri pneumokokus.

Pneumovax 23 mengandung bahan aktif berikut:
Campuran polisakarida kapsuler sangat murni dari 23 jenis pneumococcal paling umum atau invasif dari Streptococcus pneumoniae.

Pneumovax 23 tersedia:
Box, 1 syringe @ 0,5 mL – Reg No. DKIXXXXXXXXXX
Box, 10 syringe @ 0,5 mL – Reg No. DKIXXXXXXXXXX

Pemegang Izin Produk :
PT Merck Sharp Dohme Pharma Tbk
Pasuruan, Jawa Timur

Produsen:
Merck Sharp & Dohme Corp.,
West Point, PA 19486, USA
Dikemas oleh:
Merck Sharp & Dohme B.V.
Haarlem, Netherlands

Mengapa diresepkan dokter Pneumovax 23?

Dokter Anda telah menganjurkan atau memberikan Pneumovax 23 untuk membantu melindungi Anda terhadap infeksi pneumokokus yang disebabkan oleh jenis yang paling umum dari pneumococci . Vaksin ini dapat diberikan secara rutin untuk orang dewasa berusia 50 tahun atau lebih.

Dosis kedua vaksin mungkin dianjurkan di kemudian hari jika Anda berada pada risiko tinggi untuk infeksi pneumokokus .

Infeksi pneumokokus merupakan penyebab utama pneumonia, pembengkakan penutup pada otak dan sumsum tulang belakang (meningitis), infeksi telinga tengah (otitis media), dan infeksi parah dalam darah (bakteremia). Masalah-masalah ini lebih mungkin terjadi pada orang tua dan orang-orang dengan penyakit tertentu yang membuat mereka lebih rentan terhadap infeksi pneumokokus.

Apa yang harus saya ketahui sebelum vaksinasi dengan Pneumovax 23?

Siapa yang tidak boleh divaksinasi dengan Pneumovax 23?

Setiap orang yang:
alergi terhadap salah satu komponennya

Apa yang harus saya katakan ke dokter saya sebelum vaksinasi dengan Pneumovax 23?

Beritahu dokter Anda tentang masalah medis Anda memiliki atau pernah memiliki , dan tentang segala alergi.

Apa informasi penting tentang Pneumovax 23 lain yang harus saya ketahui?

Seperti vaksin lainnya, Pneumovax 23 mungkin tidak sepenuhnya melindungi semua orang yang mendapatkannya .

Penggunaan pada kehamilan.

Belum diketahui apakah vaksin berbahaya bagi bayi yang belum lahir ketika diberikan kepada wanita hamil. Katakan kepada dokter Anda jika Anda sedang hamil. Dokter Anda akan memutuskan apakah Anda harus menerima Pneumovax 23.

Penggunaan untuk ibu menyusui.

Katakan kepada dokter Anda jika Anda menyusui atau berniat untuk menyusui. Dokter Anda akan memutuskan apakah Anda harus menerima Pneumovax 23.

Penggunaan pada lansia

Individu 65 tahun dan lebih tua maupun individu yang lebih muda mungkin tidak mentolerir intervensi medis. Oleh karena itu reaksi dengan jumlah yang lebih tinggi dan/atau keparahan yang lebih besar dari pada subjek di atas 65 tahun tidak dapat dikesampingkan. Efek samping yang parah setelah vaksinasi telah dilaporkan pada beberapa orang tua yang lemah yang memiliki masalah medis lainnya yang serius.

Dapatkah saya divaksinasi dengan Pneumovax 23 dan vaksin lainnya pada saat yang sama?

Pneumovax 23 telah diberikan pada waktu yang sama dengan vaksin influenza dengan hasil yang memuaskan . Dokter Anda akan memutuskan jadwal vaksinasi.

Pneumovax 23 sebaiknya tidak diberikan pada waktu yang sama seperti ZOSTAVAX *. Untuk informasi lebih lanjut bicarakan dengan dokter Anda.

Dapatkah saya mengemudi atau mengoperasikan mesin setelah vaksinasi dengan Pneumovax 23?

Tidak ada informasi yang menunjukkan bahwa Pneumovax 23 mempengaruhi kemampuan Anda untuk mengemudi atau mengoperasikan mesin.

Apa yang harus saya tahu tentang bahan-bahan aktif dalam Pneumovax 23?

Pneumovax 23 mengandung fenol sebagai bahan aktif. Katakan kepada dokter Anda jika Anda pernah memiliki reaksi alergi terhadap bahan ini.

Bagaimana Pneumovax 23 diberikan?

Pneumovax 23 diberikan dengan dosis 0,5 mL melalui suntikan.
Dosis vaksin adalah sama untuk semua orang.

Dosis kedua Pneumovax 23 secara rutin tidak dianjurkan . Namun, bagi orang-orang dengan risiko tinggi infeksi pneumokokus yang serius , dosis kedua vaksin mungkin disarankan.

Jika anda berusia diatas 65 tahun, dan telah menerima vaksin pertama 5 tahun yang lalu pada saat usia anda kurang dari 65 tahun, anda dapat menerima dosis kedua vaksin Pneumovax 23. Konsultasikan pada tenaga medis tentang pemberian dosis ke dua ini.

Dokter Anda akan memutuskan jika dan ketika Anda memerlukan dosis kedua Pneumovax 23.

Apa efek yang tidak diinginkan yang mungkin dimiliki Pneumovax 23?

Setiap vaksin mungkin memiliki efek yang tidak diinginkan atau tidak diinginkan, yang disebut efek samping. Efek samping yang paling umum dilaporkan dengan Pneumovax 23 adalah rasa sakit, kemerahan, bengkak, kehangatan dan pengerasan pada tempat suntikan dan demam.

Efek samping lain juga dapat terjadi dengan frekuensi jarang (misalnya, kelelahan, menggigil, perasaan tidak enak badan, mual, muntah, pembesaran dan/atau kelenjar getah bening meradang, arthritis, sakit kepala, reaksi alergi, nyeri sendi, nyeri otot, perubahan sensasi kulit, gatal-gatal atau ruam, nyeri, penurunan kemampuan untuk menggerakkan anggota badan), dan beberapa di antaranya mungkin serius.

Katakan penyedia layanan kesehatan Anda atau mendapatkan bantuan darurat segera jika Anda mendapatkan salah satu dari masalah berikut setelah vaksinasi karena ini mungkin tanda reaksi alergi atau kondisi serius yang lain:

• kesulitan bernapas

• mengi
• ruam
• gatal-gatal

Reaksi di daerah di mana Anda mendapatkan suntikan mungkin lebih umum dan intens setelah suntikan kedua daripada setelah suntikan pertama.

Dokter Anda memiliki daftar yang lebih lengkap dari efek samping.

Katakan kepada dokter Anda segera tentang salah satu atau gejala yang tidak biasa lainnya. Jika kondisi tersebut terus berlangsung atau memburuk, dapatkan bantuan medis.

Bagaimana saya bisa belajar lebih banyak tentang Pneumovax 23 (dan kondisi yang diresepkan)?

Tidak semua informasi tentang vaksin ini dicetak di sini. Jika Anda memiliki pertanyaan tambahan, tanyakan kepada dokter Anda yang memiliki informasi resep penuh.