



PREVENAR 13[®] VACCINATION VS PNEUMOCOCCAL PNEUMONIA

Vaccination with Prevenar 13[®]: Understanding why, who and when

By the end of this eModule you should:

- Understand what pneumococcal pneumonia is and why you should vaccinate adults against it
- Understand what makes someone a potential candidate for vaccination
- Feel confident identifying potential candidates, and discussing vaccination with Prevenar 13[®] with them

This eModule is provided to you by Pfizer Ltd. It is not intended to replace your guidelines, protocols and SOPs.*

*SOP: Standard operating procedures

Prevenar 13[®]
Pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed)

Begin



Why vaccinate against pneumococcal pneumonia?

What is pneumonia?

Pneumonia is swelling (inflammation) of the tissue in one or both lungs, usually caused by a bacterial **infection**¹

One of the **most common symptoms** of pneumonia is a **cough**.¹ This can be dry or mucus producing (yellow, green, brownish or blood-stained)¹

Other common symptoms are:¹

- difficulty breathing
- rapid heartbeat
- fever
- feeling generally unwell
- sweating and shivering
- loss of appetite
- chest pain

As the symptoms of pneumonia **vary** and are similar to those of other chest infections, many people do not realise they have **pneumonia** until they visit a doctor¹

Adult pneumonia can be serious, and may be more common than you think¹⁻⁴

Even mild **cases of pneumonia**, which are usually treated at home, can leave sufferers with a cough that persists **2-3 weeks** after antibiotic treatment, and feeling **fatigued for even longer**^{1,2}

Severe cases of pneumonia can occur in certain '**at risk**' groups, which **may require treatment in a hospital** because they have a **higher risk of developing serious complications**¹

Each year, up to **1 in every 100** UK adults develops **pneumonia**³

In England and Wales in 2017 over **27,000** adults died of pneumonia⁴

Streptococcus pneumoniae is the most common cause of pneumonia in adults¹

Viruses and, infrequently, fungi as well as different types of bacteria such as *Haemophilus influenzae* and *Staphylococcus aureus*, can also cause pneumonia.¹

***S. pneumoniae* (pneumococcus) infections** are responsible for **approximately 37%** of all hospitalised cases of community-acquired pneumonia.⁵

Streptococcus pneumoniae is a capsular Gram-positive bacteria with more than 90 different serotypes.⁶ Prevenar 13[®] will only protect against *Streptococcus pneumoniae* serotypes included in the vaccine.

Prevenar 13[®] does not provide 100% protection against vaccine serotypes nor protect against nonvaccine serotypes.

Pneumococcal vaccination
is therefore important to
help protect individuals from
community-acquired **pneumonia**

Pneumococcal vaccination also helps to protect against invasive pneumococcal infections^{6,7}

Pneumococcal infections usually fall into one of two categories:^{6,8}

- Non-invasive pneumococcal infections: Occur when there is no evidence that the bacteria has spread to normally sterile body fluids and examples include otitis media (ear infection), sinusitis and pneumonia^{6,8}
- Invasive pneumococcal infections: Occur when bacteria are detected in normally sterile body fluids such as the blood or cerebrospinal fluid^{6,8}

Invasive pneumococcal infections include:⁶



Bacteraemic pneumonia

This is the most common invasive pneumococcal infection in adults.¹ It occurs when bacteria invade both the lungs and the bloodstream⁶



Bacteraemia/septicaemia

This occurs when pneumococcal bacteria invade the bloodstream⁶



Meningitis

This occurs when pneumococcal bacteria invade the tissues and fluids surrounding the brain and spine⁶









Who should be vaccinated against
pneumococcal pneumonia?

Many factors put adults at risk of pneumococcal infections, making them potential candidates for vaccination^{6, 9-12}

Those at increased risk include:

-  **Older adults** (those >45 years old)^{5,13}
-  **Smokers**¹
-  **Residents of care homes** or other long-term care facilities¹⁰⁻¹²
-  Those with a **suppressed immune system** e.g., patients undergoing chemotherapy and patients on long-term systemic steroids⁶

And those with **chronic conditions** including:⁶

-  **Diabetes**
-  **Liver disease** (e.g. cirrhosis)
-  **Heart disease** (e.g. ischaemic heart disease)
-  **Kidney disease**
-  **Respiratory disease** (e.g. COPD, cystic fibrosis)
-  **Asplenia or dysfunction of the spleen** (including conditions that may lead to splenic dysfunction such as coeliac syndrome)

Many of these factors can also put people at **increased risk of influenza infections**, so they may **benefit** from receiving the **flu vaccine** too.¹⁴

Pneumococcal vaccination rates among clinically at-risk adults are low^{15,16}

Data suggest that:



66% of adults aged 16–64 with chronic conditions that put them at **increased risk of pneumococcal infections** have **not yet received a pneumococcal vaccination**.¹⁵

Vaccine uptake for at-risk adults between **2017-2018** ranged from **7.0%** (chronic kidney disease) to **19.7%** (diabetes).¹⁶

Data from the Department of Health Pneumococcal Vaccine Uptake Report, survey year 2009. Uptake data were provided by 74.7% of GP practices (6258/8376) in England and refer to at-risk adults vaccinated anytime up and until 31st March 2019. More recent uptake data for this group are not available.

It is therefore important to identify **all at-risk adults** as potential candidates for vaccination.

However, as anyone can contract a pneumococcal infection, vaccination **need not be limited** to these groups.

Vaccination may also be desirable for those **attending mass gatherings**.¹⁷



When can people be
vaccinated against
pneumococcal pneumonia?



Opportunities to identify candidates for Prevenar 13[®] occur all year round

Unlike the annual flu vaccines, which have to be given seasonally, **Prevenar 13[®]** can be given at **any point in the year**.

Prevenar 13[®] could be offered to appropriate candidates during:

- **Travel vaccination consultations**
- **Smoking cessation consultations**
- Discussions regarding the initiation of a **new medicine**, e.g. during a **New Medicine Service (NMS)** appointment
- **Reviews** of a patient's **medication**, e.g. during a **Medicines Use Review (MUR)**



- **Medicals or health checks**
- **Routine appointments**
- **Prescription collection**
- **Occupational health vaccination drives**

Please note that these situations are provided as examples only. The decision on when to offer pneumococcal vaccination should be made following consideration of local guidelines and SOPs.*

*SOP - Standard operating procedures

However, flu season is a particularly important time to vaccinate people against pneumococcal pneumonia

Flu season is an important time to identify candidates for Prevenar 13[®] for clinical and practical reasons.

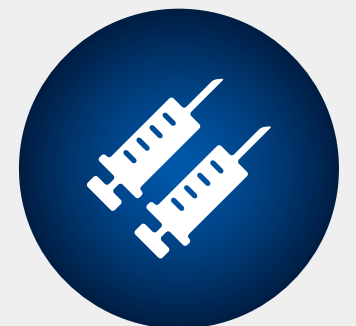
Clinical:

- Although people can contract pneumococcal infections all year round, like flu, there is **an increased incidence in the winter months**⁶
- Having the flu may increase the chance of developing pneumococcal pneumonia by up to **100 times**¹⁸



Practical:

- Adults **may be more likely to want** Prevenar 13[®] at this time
 - Targeted campaigns during flu season raise awareness of the need for vaccination among adults in general, and for at-risk groups especially
- **The vaccines can be given at the same time**⁷



Many people at risk of pneumococcal infections are also recommended to receive a flu vaccine^{6,14}

Adults recommended to receive pneumococcal and influenza vaccines by the Department of Health:^{6,14}

	Pneumococcal	Influenza
Up to 65 years Clinical at-risk groups	Those with: <ul style="list-style-type: none">• Asplenia or dysfunction of the spleen Including those with conditions that may lead to splenic dysfunction such as homozygous sickle cell disease and coeliac disease• Chronic respiratory disease• Chronic heart disease• Chronic kidney disease• Chronic liver disease• Diabetes• Immunosuppression	Those with: <ul style="list-style-type: none">• Asplenia or dysfunction of the spleen Including those with conditions that may lead to splenic dysfunction such as homozygous sickle cell disease and coeliac disease• Chronic respiratory disease• Chronic heart disease• Chronic kidney disease• Chronic liver disease• Diabetes• Immunosuppression
	AND <ul style="list-style-type: none">• Those with cochlear implants• Those with cerebrospinal fluid leaks	AND <ul style="list-style-type: none">• Those with chronic neurological disease• Those who are pregnant
65 years or older	Everyone	Everyone

Please note that only severely immunocompromised adults are entitled to receive Prevenar 13[®] via the NHS.⁶ Other risk groups are entitled to Pneumococcal Polysaccharide Vaccine (PPV) only.⁶

For the Department of Health’s full pneumococcal and influenza immunisation policy recommendations, please see the Green Book.^{6,14}



Congratulations!

You have now completed this eModule.

In summary:

- Pneumococcal vaccination is important to help protect individuals from community-acquired pneumonia
- Those at increased risk of pneumococcal infections include **older adults** (those aged >45 years); **smokers**; those with **chronic conditions** including diabetes, chronic heart, respiratory, kidney and liver diseases, asplenia or splenic dysfunction; those with a **suppressed immune system**; residents of **care homes**^{6,9-12}
- Opportunities to identify candidates for Prevenar 13® occur all year round, and include during **travel vaccination** consultations; **smoking cessation** consultations; discussions regarding a **new medication**, e.g. during a New Medicine Service (NMS) appointment; **reviews** of a **patient's medications**, e.g. during a Medicine Use Review (MUR); **medicals** or **health checks**; **routine appointments**; **prescription collection**; **occupational health vaccination drives**
- However, **flu season** is a **particularly important time** to vaccinate people against pneumococcal infections for clinical and practical reasons



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Vaccination with Prevenar 13®: Understanding why, who and when



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ABBREVIATED PRESCRIBING INFORMATION FOR ADULT INDICATION

Prevenar 13® suspension for injection

Pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed)

Presentation: Each 0.5ml dose of Prevenar 13 contains 2.2 micrograms of each of the following polysaccharide serotypes: 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19A, 19F, 23F and 4.4 micrograms of polysaccharide serotype 6B. Each polysaccharide is conjugated to the CRM₁₉₇ carrier protein and adsorbed on aluminium phosphate. 1 dose (0.5 ml) contains approximately 32 µg CRM₁₉₇ carrier protein and 0.125 mg aluminium.

Indications: Active immunisation for the prevention of invasive disease and pneumonia caused by *Streptococcus pneumoniae* in adults ≥18 years of age and the elderly. The use of Prevenar 13 should be determined on the basis of official recommendations taking into consideration the risk of invasive disease and pneumonia in different age groups, underlying comorbidities as well as the variability of serotype epidemiology in different geographical areas.

Dosage and Administration: For intramuscular injection.

Adults ≥18 years of age and the elderly: One single dose. The need for revaccination with a subsequent dose of Prevenar 13 has not been established. Regardless of prior pneumococcal vaccination status, if the use of 23 valent pneumococcal polysaccharide vaccine is considered appropriate, Prevenar 13 should be given first. **Special Populations:** Individuals who have underlying conditions predisposing them to invasive pneumococcal disease (such as sickle cell disease or HIV infection) including those previously vaccinated with one or more doses of 23-valent pneumococcal polysaccharide vaccine may receive at least one dose of Prevenar 13. In individuals with an haematopoietic stem cell transplant (HSCT), the recommended immunisation series consists of four doses of Prevenar 13, each of 0.5 ml. The primary series consists of three doses, with the first dose given at 3 to 6 months after HSCT and with an interval of at least 1 month between doses. A fourth (booster) dose is recommended 6 months after the third dose. **Contra-indications:** Hypersensitivity to the active substances, to any of the excipients, or to diphtheria toxoid. As with other vaccines, the administration of Prevenar 13 should be postponed in subjects suffering from acute, severe febrile illness. However, the presence of a minor infection, such as a cold, should not result in the deferral of vaccination.

Warnings and Precautions: Do not administer intravascularly. Appropriate medical treatment and supervision must be available in case of anaphylaxis. It should not be given to individuals with thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injection, but may be given subcutaneously if the potential benefit clearly outweighs the risks. Prevenar 13 will only protect against *Streptococcus pneumoniae* serotypes included in the vaccine, and will not protect against other microorganisms that cause invasive disease and pneumonia. As with any vaccine, Prevenar 13 may not protect all individuals receiving the vaccine from pneumococcal disease. Individuals with impaired immune responsiveness, whether due to the use of immuno-suppressive therapy, a genetic defect, human immunodeficiency virus (HIV) infection, or other causes, may have reduced antibody response to active immunisation. Safety and immunogenicity data are available for a limited number of individuals with sickle cell disease, HIV infection, or with an HSCT. Safety

and immunogenicity data for Prevenar 13 are not available for individuals in other specific immuno-compromised groups (e.g., malignancy, or nephrotic syndrome) and vaccination should be considered on an individual basis.

Adults aged 50 years and older: When Prevenar 13 was given concomitantly with trivalent inactivated influenza vaccine (TIV), the immune responses to Prevenar 13 were lower compared to when Prevenar 13 was given alone, however, there was no long-term impact on circulating antibody levels. The immune responses to Prevenar 13 were noninferior when Prevenar 13 was given concomitantly with quadrivalent inactivated influenza vaccine (QIV) compared to when Prevenar 13 was given alone. As with concomitant administration with trivalent vaccines, immune responses to some pneumococcal serotypes were lower when both vaccines were given concomitantly.

Fertility, Pregnancy & Lactation: There are no data from the use of pneumococcal 13-valent conjugate vaccine in pregnant women. Therefore the use of Prevenar 13 should be avoided during pregnancy.

It is unknown whether pneumococcal 13-valent conjugate is excreted in human milk. **Side Effects:** Adverse reactions reported in clinical studies or from the post-marketing experience are listed in this section per system organ class, in decreasing order of frequency and seriousness. **Adults ≥18 years of age, and the elderly: Very common** (≥ 1/10): Decreased appetite, headaches, diarrhoea, vomiting, rash, chills; fatigue; injection-site erythema; injection-site induration/swelling; injection-site pain/tenderness; limitation of arm movement, arthralgia; myalgia. **Common** (≥ 1/100 to < 1/10): Vomiting, pyrexia.

Uncommon (≥ 1/1,000 to < 1/100): Nausea, hypersensitivity reaction including face oedema, dyspnoea, bronchospasm, lymphadenopathy localized to the region of the injection site. **Additional information in special populations:** Adults with HIV infection have similar frequencies of adverse reactions, except that pyrexia and vomiting were very common and nausea common. Adults with an HSCT have similar frequencies of adverse reactions, except that pyrexia and vomiting were very common. **Legal Category:** POM. **Package Quantities:** Pack of 1 single-dose pre-filled syringe (with separate needle) or pack of 10 single-dose pre-filled syringes. **Cost:** Cost for supply outside the UK routine childhood immunisation programme: Single-dose pre-filled syringe (with separate needle) pack of 1: £49.10; single-dose pre-filled syringe pack of 10: £491.

Marketing Authorisation Numbers: Single-dose pre-filled syringe (with separate needle) pack of 1: EU/1/09/590/002, single-dose pre-filled syringe pack of 10: EU/1/09/590/003. **Marketing Authorisation**

Holder: Pfizer Europe MA EEIG, Boulevard de la Plaine 17, 1050 Bruxelles, Belgium.

For full prescribing information and details of other side effects see Summary of Product Characteristics.

Further information is available on request from Medical Information Department at Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS, UK. Last revised: 09/2018. Ref: PN Adult 5_0.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Pfizer Medical Information on 01304 616161