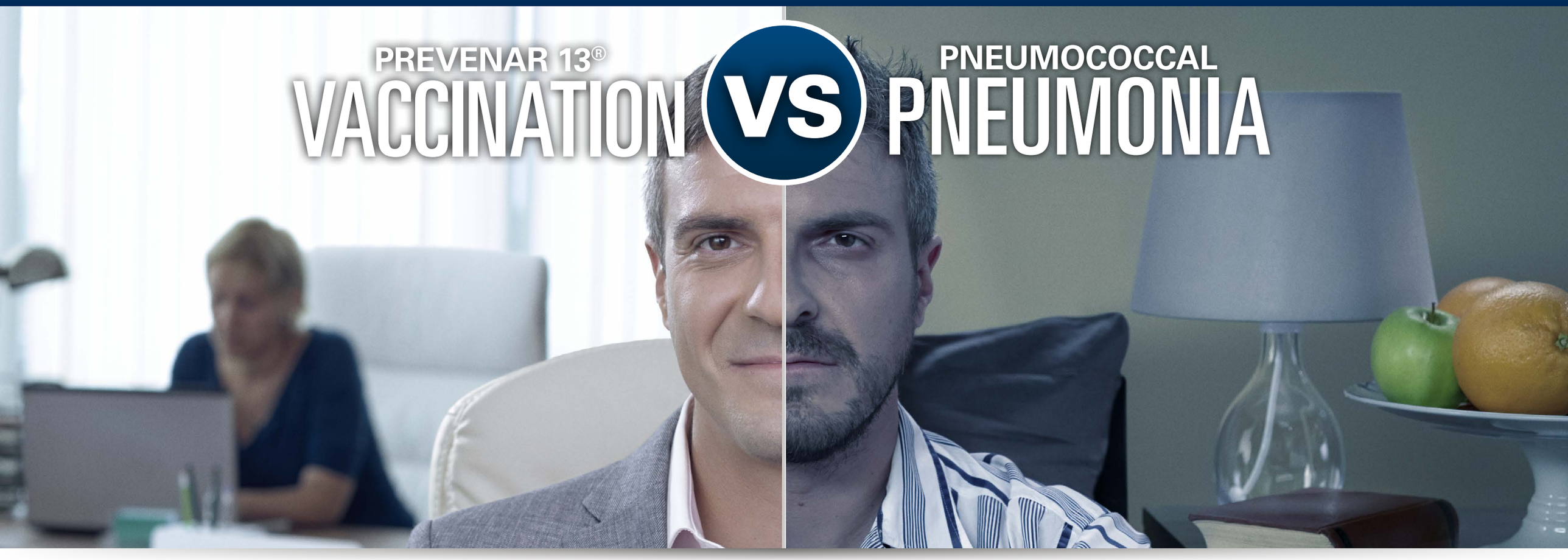


Prevenar 13®: The vaccination process

By the end of this eModule you should:

- Understand the steps you need to take before, during, and after administering Prevenar 13®
- Feel confident when vaccinating adults with Prevenar 13®

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

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

* SOP – Standard operating procedures

Begin

PP-PNA-GBR-0393 January 2020

Pre-administration

Before administering Prevenar 13®

Take steps to ensure your consulting room is prepared

As with all vaccines, there are steps you should take to prepare your consulting room prior to administration of Prevenar 13®:

Ensure the **sharps bin** is near to where you will be administering the vaccine, so that you can dispose of the syringe immediately.

Ensure your **anaphylaxis kit** is accessible, full, and that the components are in-date.

Ensure you have **cotton wool pads** to hand, so pressure can be applied immediately after administration.

Ensure that Prevenar 13® has been stored correctly: in a **refrigerator**, at temperatures between 2°C and 8°C.[1]

Prevenar 13® is stable for 4 days if it is accidentally left at room temperature (up to 25°C).[1] After this time the vaccine should be used immediately or discarded.[1] The vaccine must not be frozen.[1]

Before administering Prevenar 13®

Provide every potential recipient with the Prevenar 13® Patient Information Leaflet, then complete the following pre-administration checklist

Question 1

Is the recipient allergic to:

a. Pneumococcal polysaccharides?
b. Diphtheria toxoid?
c. Aluminium phosphate?
d. Sodium chloride?
e. Succinic acid?
f. Polysorbate 80?
g. Water for injections?

Or are they pregnant?

→ **YES** →

DO NOT VACCINATE[1]

Prevenar 13® must not be administered to people who are allergic to anything in this list, or pregnant women.

→ **NO** → **Go to Question 2**

Before administering Prevenar 13®

Provide every potential recipient with the Prevenar 13® Patient Information Leaflet, then complete the following pre-administration checklist

Question 2

Does the recipient have acute and severe febrile illness (fever)?

YES →

POSTPONE VACCINATION[1]

Please note that minor infections, such as a cold, should not delay vaccination.[1]

NO → **Go to Question 3**

Before administering Prevenar 13®

Provide every potential recipient with the Prevenar 13® Patient Information Leaflet, then complete the following pre-administration checklist

Question 3

Does the recipient have a bleeding disorder e.g., thrombocytopenia?

YES → Do the benefits of vaccination outweigh the risk of bleeds?

NO → **DO NOT VACCINATE**[1]

Individuals with a bleeding disorder must not be given Prevenar 13® as an intramuscular injection. It may be given subcutaneously if the potential benefit clearly outweighs the risks.[1]

YES

Prevenar 13® may be administered **SUBCUTANEOUSLY**[1]

NO → Go to Question 4

Before administering Prevenar 13®

Provide every potential recipient with the Prevenar 13® Patient Information Leaflet, then complete the following pre-administration checklist

Question 4

Is the recipient immunocompromised?

→ **YES** →

Inform them that they may have a reduced antibody response to Prevenar 13®[1]

→ **NO** →

Go to Question 5

Before administering Prevenar 13®

Provide every potential recipient with the Prevenar 13® Patient Information Leaflet, then complete the following pre-administration checklist

Question 5

Has the recipient ever received Pneumococcal Polysaccharide Vaccine (PPV)?

YES → Did they receive it in the last 6 months?

YES → Suggest they **POSTPONE** vaccination until at least 6 months have passed.[2]

The Green Book recommends that at least 6 months should elapse before administering Prevenar 13® to people who have previously received PPV.[2]

NO → Did they receive it in the last 6 months?

NO → **Go to Question 6**

NO → **Go to Question 6**

Before administering Prevenar 13®

Provide every potential recipient with the Prevenar 13® Patient Information Leaflet, then complete the following pre-administration checklist

Question 6

Has the recipient read the Prevenar 13® Patient Information Leaflet, and thus been informed of the benefits and risks associated with receiving Prevenar 13®?

NO → Ask them to read the Prevenar 13® Patient Information Leaflet

YES → Go to Question 7

Before administering Prevenar 13®

Provide every potential recipient with the Prevenar 13® Patient Information Leaflet, then complete the following pre-administration checklist

Question 7

Has the recipient given informed consent to receive Prevenar 13®?

→ **YES** → **VACCINATE**

→ **NO** → **DO NOT VACCINATE** until informed consent has been obtained

Administration

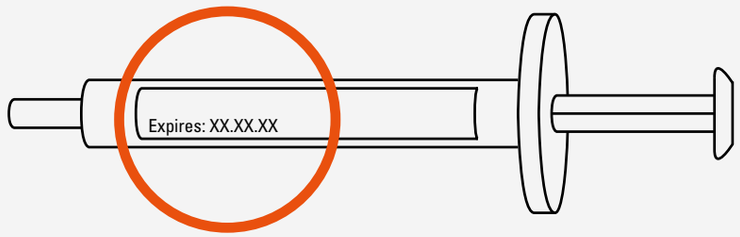
When administering Prevenar 13®

Follow the step-by-step process outlined here

Step 1 – Prepare the vaccine

- First check that the **expiry date** printed on the syringe has not passed
- Then, **shake the vaccine well**.[1] Prevenar 13® can separate during storage to form a white deposit in a clear liquid; the vaccine should be shaken until these layers combine to form a **uniform white suspension**[1]
- Next, **check the vaccine visually** for any foreign particles and/or an abnormal physical appearance.[1] **Do not use the vaccine if either are found**[1]
- Finally, attach a needle and **expel any air** from the syringe[1]

You should also ensure you **record the batch number** and **expiry date** of the vaccine in the recipient's notes.



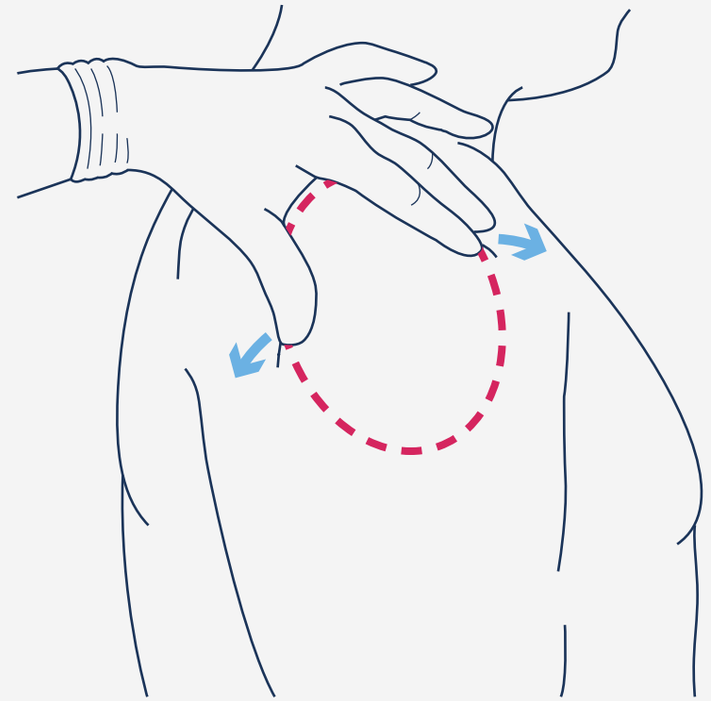
Please note the method described here is intramuscular injection, which should be used in all patients apart from those with bleeding disorders. For details of the subcutaneous method of injection, which should be used in patients with bleeding disorders, please consult the Green Book.[3]

When administering Prevenar 13®

Follow the step-by-step process outlined here

Step 2 – Prepare the injection site

- Prevenar 13® should be administered **intramuscularly**, preferably into the **deltoid muscle at the top of the arm** or alternatively into the vastus lateralis muscle in the outer thigh[1]
- Once an injection site has been chosen, stretch the skin, using your thumb and index finger[3]

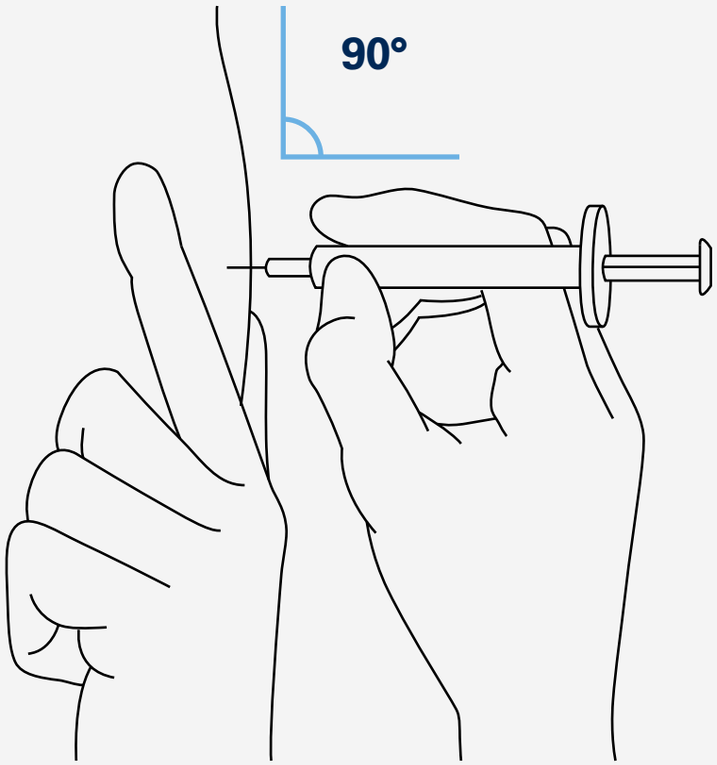


When administering Prevenar 13®

Follow the step-by-step process outlined here

Step 3 – Administer the vaccine

- The needle should be inserted into the **muscle at a 90° angle** until just a small part of the needle shaft remains visible[3]
- Once the needle is inserted, **depress the plunger** to administer the vaccine. The entire dose should be administered in one go



When administering Prevenar 13®

Follow the step-by-step process outlined here

Step 4 – Withdraw the needle and dispose of the syringe

- Once the vaccine has been administered, withdraw the needle and **apply gentle pressure** to the injection site using a **cotton wool pad**
- The syringe should then be **immediately put into a sharps bin**[3]

Post-administration

After administering Prevenar 13®

Ensure that you provide recipients with the following information

Side effects

Remind the recipient that they should talk to a healthcare professional if they have a side effect following administration of the vaccine. Explain that this includes the potential side effects you informed them of before administration (which are provided in the Patient Information Leaflet), and any other side effects they have.

Explain that side effects can also be reported directly via the Yellow Card Scheme, using the website: https://yellowcard.mhra.gov.uk/

Level of protection

Remind the recipient that, as with any vaccine, Prevenar 13® will not protect everyone who is vaccinated, and although Prevenar 13® helps to protect against 13 of the most harmful types of *Streptococcus pneumonia*, it won't protect against all types.[1]

Recipients should therefore be reminded to talk to a healthcare professional if they develop symptoms of a pneumococcal infection.

Revaccination

Advise the recipient that Prevenar 13® is a one-dose course and the need for revaccination with a subsequent dose of Prevenar 13® has not been established.[1]

Congratulations!

You have now completed this eModule.

In summary:

- Take steps to ensure your consulting room is prepared before you administer Prevenar 13®
- Complete the pre-administration checklist with every potential recipient
- Make sure you administer Prevenar 13® according to best practice guidelines, and follow the step-by-step process identified in this eModule

References

1. Prevenar 13® Summary of Product Characteristics. June 2019.
2. Public Health England. The Green Book [published 2013, updated 2018]. Chapter 25: Pneumococcal. Available at https://www.gov.uk/government/publications/pneumococcal-the-green-book-chapter-25. Last accessed January 2020.
3. Public Health England. The Green Book [published 2013, updated 2018]. Chapter 4: Immunisation procedures. Available at https://www.gov.uk/government/publications/immunisation-procedures-the-green-book-chapter-4. Last accessed January 2020.

Prevenar 13®: The vaccination process

Back

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 CRM_{197} carrier protein and adsorbed on aluminium phosphate. 1 dose (0.5 ml) contains approximately 32 µg CRM_{197} 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