PNEUMOVAX® 23
Solution for injection in a pre-filled syringe
Pneumococcal Polysaccharide Vaccine

PRESCRIBING INFORMATION
Refer to Summary of Product Characteristics (SmPC) before prescribing

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 MSD, UK (Tel: 0208 1548000).
By clicking the above link you will leave the MSD website and be taken to the MHRA website.

PRESENTATION
Single dose containing 0.5 ml of solution. Each dose contains 25 mcg of each of the following 23 pneumococcal polysaccharide serotypes: 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19F, 19A, 20, 22F, 23F and 33F, dissolved in isotonic saline solution containing 0.25% phenol.

USES
For active immunisation against pneumococcal disease in children aged from 2 years, adolescents and adults.

DOSAGE AND ADMINISTRATION
Immunisation schedules based on official recommendations. Single dose of 0.5 ml given by intramuscular or subcutaneous injection. *Special dosing:* give at least 2 weeks before elective splenectomy or the initiation of chemotherapy or other immunosuppressive treatment. Do not administer during or any sooner than 3 months after completion of chemotherapy or radiation therapy. Vaccinate patients with HIV infection as soon as possible after diagnosis confirmed. *Revaccination:* healthy people should not be re-vaccinated routinely. Revaccination at intervals of less than 3 years is not recommended because of an increased risk of adverse reactions. Revaccination may be considered for patients aged 10 years or over at increased risk of serious pneumococcal infection who were vaccinated more than 5 years earlier or for those known to have a rapid decline in pneumococcal antibody levels. Re-vaccination at 3 years may be considered for selected populations (e.g. asplenics) for adults and children of 10 years and above. Children between 2 and 10 years should only be considered for re-vaccination after 3 years if they are at high risk of pneumococcal infection (e.g. those with nephrotic syndrome, asplenia or sickle cell disease).

CONTRA-INDICATIONS
Hypersensitivity to any component of the vaccine.

PRECAUTIONS
Ensure appropriate facilities and medication are available in case of anaphylaxis. Delay vaccination in presence of significant febrile illness or other active infection, except where delay involves greater risk. Do not inject intravascularly or intradermally. If the vaccine is administered to immunosuppressed patients, reduced serum antibody response may not provide adequate protection after a first or second dose. Required prophylactic pneumococcal antibiotic therapy should not be stopped after vaccination. Vaccine may not prevent infection following basilar skull fracture or external communication with cerebrospinal fluid. Vaccine may not provide complete protection in all recipients. Advise patients at high risk of serious pneumococcal infection to seek medical advice immediately in the event of severe, sudden febrile illness. Reduced immunogenicity of Zostavax® has been reported after concurrent administration with pneumococcal polysaccharide vaccine (PPV) in a small clinical trial. Data collected in a large observational study did not indicate an increased risk of developing herpes zoster after concomitant administration of the two vaccines. PPV is not effective for the prevention of acute otitis media, sinusitis and other common upper respiratory tract infections. *Pregnancy and lactation*: Do not use during pregnancy unless clearly necessary and use with caution when administered to a nursing mother.

SIDE EFFECTS
Refer to SmPC for complete information on side-effects.
Very common: fever (≤ 38.8°C) and injection site reactions such as pain, soreness, erythema, warmth, swelling and induration. Other reported side effects that may potentially be serious include thrombocytopenia in patients with stabilised idiopathic thrombocytopenic purpura, haemolytic anaemia in patients who

have had other haematologic disorders, leukocytosis, lymphadenitis, lymphadenopathy, anaphylactoid reactions, serum sickness, angioneurotic oedema, Guillain-Barré Syndrome, radiculoneuropathy, febrile convulsions and injection site cellulitis.

PACKAGE QUANTITIES AND BASIC NHS COST

Pneumovax 23: 1 X single dose pre-filled syringe with 2 needles: £16.80

Marketing Authorisation number:
PL 53095/0005

Marketing Authorisation Holder:
Merck Sharp & Dohme (UK) Limited,
120 Moorgate, London EC2M 6UR,
United Kingdom

Legal category: POM

Date of review of prescribing information: February 2021

PI.PNX-PFS.21.UK.7621.MAT.RCN019131