Product Name: PNEUMOVAX 23 Solution for Injection	Component: English Patient Information Leaflet Date Approved: 16 July 2020

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

PNEUMOVAX® 23 (Pneumococcal Vaccine Polyvalent, MSD) Solution for Injection

WHAT PNEUMOVAX 23 CONTAINS

PNEUMOVAX 23 (pneumococcal vaccine polyvalent) is an injectable vaccine to help prevent infections, such as pneumonia and bacteraemia (severe infection in the blood), caused by certain types of pneumococcal bacteria.

PNEUMOVAX 23 contains the following inactive ingredients: sodium chloride, liquefied phenol (as preservative) and water for injection.

WHAT PNEUMOVAX 23 IS USED FOR

Your doctor has recommended or administered PNEUMOVAX 23 to help protect you or your child against pneumococcal infections caused by the most common types of pneumococci. The vaccine can be administered routinely to persons 50 years of age or older. The vaccine can also be administered to persons 2 years of age and older if:

- they have chronic illnesses (e.g. heart disease, lung disease, liver disease or diabetes mellitus), alcoholism or cerebrospinal fluid leaks.
- they do not have a spleen or have a spleen that does not function properly.
- they have HIV infection, Hodgkin's disease, lymphoma, multiple myeloma, leukaemia, generalised malignancy, chronic renal failure or nephrotic syndrome, are receiving cancer chemotherapy or other immunosuppressive therapy (including corticosteroids) or have organ or bone marrow transplantation.
- they are living in special environments or social settings with an increased risk of pneumococcal infection.

A second dose of the vaccine may be recommended at a later date if you are at high risk for a pneumococcal infection.

Pneumococcal infection is a leading cause of death throughout the world and is a major cause of pneumonia, swelling of the coverings on the brain and spinal cord (meningitis), middle ear infections (otitis media) and a severe infection in the blood (bacteraemia). These problems are more likely to occur in older people and those with certain diseases that make them more susceptible to a pneumococcal infection.

BEFORE TAKING PNEUMOVAX 23

Who should not be vaccinated with PNEUMOVAX 23?

Anyone who is allergic to any of its components.

Take special care with PNEUMOVAX 23

Tell your doctor about any of the following that apply to you:

Any medical problem you or your child have or have had, and about any allergies.

What other important information about PNEUMOVAX 23 should I know?

As with other vaccines, PNEUMOVAX 23 may not fully protect all those who get it.

Use in children

PNEUMOVAX 23 can be used in children 2 years of age and older, and is not recommended for use in children below 2 years of age.

Use in the elderly

Elderly patients from 65 years of age.

Individuals 65 years and older may not tolerate medical interventions as well as younger individuals. Therefore, a higher number and/or a greater severity of reactions in some older individuals cannot be ruled out.

Pregnancy and Breastfeeding

Use in pregnancy

It is not known whether the vaccine is harmful to an unborn baby when administered to a pregnant woman. Tell your doctor if you are pregnant. Your doctor will decide if you should receive PNEUMOVAX 23.

Use in breastfeeding

Tell your doctor if you are breastfeeding or intend to breastfeed. Your doctor will decide if you should receive PNEUMOVAX 23.

If you are pregnant or breastfeeding your baby while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Taking other medicines with PNEUMOVAX 23

Can I or my child be vaccinated with PNEUMOVAX 23 and other vaccines at the same time?

PNEUMOVAX 23 has been administered at the same time as influenza vaccines with satisfactory results. Your doctor will decide the vaccination schedule.

PNEUMOVAX 23 should not be given at the same time as ZOSTAVAX. For more information talk to your doctor.

If you are taking medicines on a regular basis, using PNEUMOVAX 23 at the same time with another medicine may cause undesirable interactions. Please

consult your doctor, pharmacist or other healthcare professional for advice.

Driving and using machinery

There is no information to suggest that PNEUMOVAX 23 affects your ability to drive or operate machinery.

What should I know about the inactive ingredients in PNEUMOVAX 23?

PNEUMOVAX 23 contains phenol as an inactive ingredient. Tell your doctor if you or your child has ever had an allergic reaction to this ingredient.

HOW TO TAKE PNEUMOVAX 23

PNEUMOVAX 23 is given by injection.

The dose of the vaccine is the same for everyone.

A second dose of PNEUMOVAX 23 routinely is not recommended. However, for persons at the highest risk of serious pneumococcal infection, a second dose of the vaccine may be recommended.

Your doctor will decide if and when you need a second dose of PNEUMOVAX 23.

Do not share medicines prescribed for you with any other person.

If you take more PNEUMOVAX 23 than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

POSSIBLE SIDE EFFECTS

Any vaccine may have unintended or undesirable effects, so-called side effects. The most common side effects reported with PNEUMOVAX 23 are soreness, redness, swelling, warmth and hardening at the injection site and fever.

Other side effects may also occur rarely (e.g. fatigue, chills, feeling unwell, nausea, vomiting, enlarged and/or inflamed lymph glands, arthritis, headache, allergic reaction, joint pain, muscle pain, altered skin sensation, hives or rash, pain, decreased ability to move limbs and seizures in children due to fever) and some of these may be serious.

Your doctor has a more complete list of side effects.

Tell your healthcare professional or get emergency help right away if you get any of the following problems after vaccination, because these may be signs of an allergic reaction or other serious conditions:

- difficulty breathing
- wheezing
- rash

- hives.

Tell your doctor promptly about any of these or any other unusual symptoms. If the condition persists or worsens, seek medical attention.

Not all side effects reported for PNEUMOVAX 23 are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

How can I learn more about PNEUMOVAX 23 (and the condition for which it is prescribed)?

Not all the information about this vaccine is printed here. If you have any additional questions, ask your doctor who has the full prescribing information.

STORAGE AND DISPOSAL INFORMATION

Store at 2 to 8 °C.

Keep all medicines safely out of reach and sight of children.

PRESENTATION

PNEUMOVAX 23 is available in a pack containing 1 or 10 single-dose, pre-filled 1,5 mL glass syringes containing 0,5 mL liquid vaccine.

IDENTIFICATION OF PNEUMOVAX 23

PNEUMOVAX 23 is a clear, colourless liquid. The vaccine is used directly as supplied. No dilution or reconstitution is necessary.

REGISTRATION NUMBER

T/30.1/0544

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