Package leaflet: Information for the user

PNEUMOVAX® 23 solution for injection in pre-filled syringe

Pneumococcal Polysaccharide Vaccine

For adults and children 2 years and above.

Read all of this leaflet carefully before you or your child receive this vaccine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This vaccine has been prescribed for you or your child. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours or your child's.
- If you or your child get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What PNEUMOVAX 23 is and what it is used for

PNEUMOVAX 23 is a pneumococcal vaccine. Vaccines are used to protect you or your child against infectious diseases. Your doctor has recommended that you or your child (two years of age and older) have the vaccine to help protect against severe infections caused by bacteria that are called pneumococci.

Pneumococci can cause infections of the lungs (especially pneumonia) and of the coverings over the brain and spinal cord (meningitis) and in the blood (bacteraemia or septicaemia). The vaccine will only be able to protect you or your child against pneumococcal infections that are due to the types of these bacteria that are included in the vaccine. However, the 23 pneumococcal types in the vaccine include those that cause almost all (about nine out of ten) infections caused by pneumococci.

When the vaccine is given to you or your child, the body’s natural defences make antibodies that help to protect against pneumococcal infections.

Pneumococcal infections occur throughout the world and can occur in anyone at any age, but are most likely in:
- elderly people.
- people who have lost their spleen or whose spleen is not working.
- people who have low resistance to infections due to longstanding illnesses or infections (such as heart disease, lung disease, diabetes mellitus, kidney disease, liver disease or HIV infection).
- people who have low resistance to infections due to treatment that they have had for some illnesses (such as cancer).

Pneumococcal infections of the coverings of the brain and spinal cord (meningitis) sometimes occur after injuring and cracking the skull and very rarely after certain medical operations. The vaccine may not be able to prevent all of these infections.

Also, pneumococcal infections can occur in the sinuses, ears, and in other parts of the body. The vaccine is not thought likely to protect you or your child against these more minor kinds of infections.

2. What you need to know before you or your child use PNEUMOVAX 23

PNEUMOVAX 23 is for use only in persons who are at least two years old. This is because younger children do not reliably respond to the vaccine.

To make sure that the vaccine is suitable for you or your child, it is important to tell your doctor or nurse if any of the points below apply to you or your child. If there is anything you do not understand, or if you are not sure, ask your doctor or nurse to explain. As with other vaccines, PNEUMOVAX 23 may not fully protect all those who get it.

Do not use PNEUMOVAX 23 if you or your child are allergic (hypersensitive) to pneumococcal polysaccharide vaccine or any of the ingredients that are listed in section 6.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before vaccination if:
- you or your child has an infection with a high temperature, as vaccination may need to be delayed until you or your child has recovered.

You should also tell your doctor before vaccination if:
- you or your child has a low resistance to infections because of a course of treatment (such as drugs or radiation treatment for cancer).
- you or your child has a longstanding illness or an infection that may have lowered resistance to pneumococcal infections.

In these cases vaccination may need to be delayed and even then it may not protect you as well as it protects healthy people.

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

Other medicines and PNEUMOVAX 23
Tell your doctor or pharmacist if you or your child are using, have recently used or might use any other medicines.

PNEUMOVAX 23 can be given at the same time as influenza vaccine as long as different injection sites are used. Most people are able to respond to both vaccines at the same time so that they can be protected against both infections.

For information about the administration of PNEUMOVAX 23 and ZOSTAVAX at the same time, talk to your doctor or health care provider.

If you or your child are already taking antibiotics to prevent pneumococcal infection, these should not be stopped after vaccination. Also, even after having the vaccine, it is still important that you see a doctor and get antibiotic treatment quickly if you think that you or your child may have any type of infection and you or your child have been told that you have a high risk of getting a pneumococcal infection (for example, if you have no spleen or it is not working properly).

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby or to breast-feed, ask your doctor or pharmacist for advice before taking this vaccine.

Driving and using machines
There is no information to suggest that the vaccine will affect your ability to drive or use machines.

PNEUMOVAX 23 contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially sodium-free.

3. How to use PNEUMOVAX 23

The vaccination should be given by a doctor or nurse who has been trained in the use of vaccines. The vaccine should be given in a surgery or clinic because there is equipment to deal with any uncommon severe allergic reaction to the injection.

Always use this vaccine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The vaccine is given as an injection into a muscle or deep under the skin. Your doctor or nurse will avoid giving you or your child the injection either into the skin or into a blood vessel.

The vaccine is sometimes given before (usually at least two weeks before) the planned date for taking out your spleen or for starting special treatments for cancer. If you or your child have already started or have finished special treatments, the vaccine may be delayed for about three months.

When the vaccine is given to people who are HIV positive, it is usually given as soon as the test result is known.

You or your child will receive one dose of the vaccine. A second dose of the vaccine is not usually given until at least three years after the first dose. Healthy people do not usually need to have a second dose. However, for persons at increased risk of serious pneumococcal infection (such as those who have no spleen or a spleen that does not work properly), further doses of the vaccine may be recommended, usually between 3 and 5 years after the first dose. A repeat dose is not usually recommended within 3 years of the first dose due to a higher risk of side effects.

Your doctor or nurse will be able to decide if and when you or your child need a further dose of the vaccine.

If you use more PNEUMOVAX 23 than you should
There have been no reports of overdose with the vaccine. Overdose is very unlikely because the vaccine is provided in single dose, pre-filled syringe and is given by a doctor or nurse.

4. Possible side effects

Like all vaccines and medicines, PNEUMOVAX 23 can cause side effects, although not everybody gets them.

Allergic Reactions
You must seek urgent medical help if you or your child experience any of the symptoms, listed below, or other serious symptoms after vaccination:
- difficulty in breathing, blue discolouration of the tongue or lips,
- low blood pressure (causing dizziness) and collapse,
- fever, generally feeling unwell with pains or even inflammation and swelling in the joints and muscle pain,
- swelling of the face, lips, tongue and/or throat and neck,
- swelling of the hands, feet or ankles,
- hives (inflamed wheals on the skin) and rashes.

If serious allergic reactions occur, they often do so very soon after the injection, while still in the clinic.

Side Effects
The most common reactions (may affect more than 1 in 10 people) reported are soreness, pain, redness, warmth, swelling and hardening at the injection site, and fever. These reactions tend to be more common after the second dose of the vaccine than after the first dose.

Other side effects include:
Rare (may affect up to 1 in 1,000 people):
- extensive swelling of the vaccinated limb.

Not known (frequency cannot be estimated from the available data):
- decreased mobility of the injected limb,
- feeling tired,
- feeling generally unwell,
- uncontrollable shivering,
- feeling sick or being sick,
- enlarged and/or inflamed glands,
- pain, inflammation and swelling of the joints and muscle pains,
- a drop in the number of certain types of particles in the blood called platelets in people who already have low numbers of these due to another illness called ITP that causes a higher risk of bleeding and bruising,
- headache, altered skin sensation or pins and needles, decreased limb mobility, numbness and weakness of the legs and arms (including an illness called Guillain-Barré syndrome),
- an increase in the value of a blood test that is a measure of inflammation in the body (C-reactive protein (CRP)),
- patients who have had blood disorders may develop destruction of red blood cells leading to an inadequate number of red blood cells (haemolytic anaemia),
- an increase in the number of certain types of white blood cells,
- a fit (convulsion) associated with a high temperature.

Reporting of side effects
If you or your child get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.
Ireland: HPRA Pharmacovigilance, website: www.hpra.ie
Malta: ADR Reporting, Website: www.medicinesauthority.gov.mt/adrportal

5. How to store PNEUMOVAX 23

Keep this vaccine out of the sight and reach of children.

Do not use this vaccine after the expiry date which is stated on the box after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C - 8°C). Do not freeze.

Your doctor or nurse will check that the liquid is clear and colourless and that there are no large particles in it before giving you or your child the vaccine.

Do not throw away any vaccines via wastewater or house hold waste. Ask your pharmacist how to throw away vaccines you no longer need. These measures will help protect the environment.

6. Contents of the pack and other information

What PNEUMOVAX 23 contains
0.5 millilitre dose contains the following:

- Active ingredients - 25 micrograms (a very small amount) of each of 23 types of polysaccharide from bacteria known as pneumococci. The 23 types of pneumococcal polysaccharide in the vaccine are types 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19F, 19A, 20, 22F, 23F and 33F.
- Other ingredients - phenol, sodium chloride and water for injections.

The vaccine contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium-free'.

What PNEUMOVAX 23 looks like and contents of the pack
It is provided as a solution for injection in pre-filled syringe (0.5 mL).
It is available in pack containing 1 or 10 pre-filled syringes without needle.
It is available in pack containing 1 or 10 pre-filled syringes with 1 separate needle.
It is available in pack containing 1 or 10 pre-filled syringes with 2 separate needles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Ireland
Merck Sharp & Dohme Ireland (Human Health) Limited,
Red Oak North, South County Business Park,
Leopardstown,
Dublin 18,
Ireland

Malta
Merck Sharp & Dohme B.V.
Waarderweg 39
Haarlem, 2031 BN
Netherlands

Manufacturer:
Merck Sharp & Dohme B.V., Waarderweg 39, 2031 BN Haarlem, The Netherlands.

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Austria; Belgium; Bulgaria; Croatia; Cyprus; Czech Republic; Germany; Greece; Ireland; Luxemburg; Malta; Netherlands; Portugal; Romania; Slovakia; Slovenia; Spain; United Kingdom (Northern Ireland)	PNEUMOVAX 23
Denmark; Finland; France; Italy; Iceland; Lithuania; Norway; Sweden	PNEUMOVAX

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