

PNEUMOVAX[®] 23

Pneumococcal Vaccine Polyvalent; Pneumococcal purified capsular polysaccharides

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about PNEUMOVAX 23 (pronounced new-mo-vax). It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines and vaccines have risks and benefits. Your doctor has weighed the risks of you being given PNEUMOVAX 23 against the benefits they expect it will have for you.

If you have any concerns about being given this vaccine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What PNEUMOVAX 23 is used for

PNEUMOVAX 23 is a vaccine used to help prevent infections caused by certain types of germs or bacteria called pneumococcus (pronounced new-mo-kock-us). PNEUMOVAX 23 helps protect against the most common types of pneumococcal bacteria.

PNEUMOVAX 23 is not recommended for use in children below 2 years of age.

It can be given to children 2 years of age and older, teenagers and adults who:

- have no spleen or a spleen that does not function properly, including sickle cell disease

- have a decreased immune system and are at increased risk of pneumococcal infection, for example, people with organ transplants, HIV or certain cancers
- have long-term diseases and are at increased risk of pneumococcal infection
- have leakage of fluid from around the brain and spinal cord

It can also be given to Aboriginal and Torres Strait Islander people over 50 years of age.

In addition, PNEUMOVAX 23 is recommended as a routine vaccination for people aged 65 years and older.

Pneumococcal infection is an important cause of death worldwide. Protection against pneumococcal infection is important because the germs or bacteria can cause serious diseases such as:

- meningitis, an infection of the brain and/or spinal cord
- pneumonia, an infection of the lungs
- a severe infection of the middle ear
- a severe infection in the blood.

Groups of people who are at increased risk of pneumococcal disease include those who have poor immune systems, such as people with organ transplants, certain cancers and HIV/AIDS. Other people who are at risk of pneumococcal disease include those with no spleen, those with long-term problems of the heart, lung, kidney or liver, diabetes mellitus, alcoholics and people aged 65 years and older, and those who

smoke. In Australia, the vaccine is currently recommended by the National Health and Medical Research Council (NHMRC) for tobacco smokers.

Infection from pneumococcal bacteria usually occurs when you come into contact with an infected person. The infection may be spread when an infected person coughs or sneezes near another person. Apart from certain diseases, other situations that may increase the risk of infection include:

- being around groups of other children (e.g. Daycare)
- living in the same household as someone who is infected.

How it works

PNEUMOVAX 23 works by causing your body to produce its own protection against pneumococcal infection. It does this by making disease-fighting substances called antibodies to fight the bacteria. The vaccine itself cannot cause the infection. If a vaccinated person comes into contact with live bacteria, the body is usually ready and produces antibodies to destroy it.

However, as with all vaccines, 100% protection against pneumococcal disease cannot be guaranteed.

The chance of a severe reaction from PNEUMOVAX 23 is very small, but the risks from not being vaccinated may be very serious.

PNEUMOVAX 23 only protects against infections caused by the most common types of pneumococcal bacteria, not against the less common types of pneumococcal bacteria or other germs.

Before you are given PNEUMOVAX 23

When you or your child must not be given it

Do not have PNEUMOVAX 23 if:

- you have an allergy to PNEUMOVAX 23 or any of the ingredients listed at the end of this leaflet
- the expiry date on the pack has passed

If the vaccine is used after the expiry date has passed, it may not work.

If you are not sure whether you or your child should be given PNEUMOVAX 23, talk to your doctor.

Do not give PNEUMOVAX 23 to children under 2 years of age.

The safety and effectiveness of PNEUMOVAX 23 in children below the age of 2 years have not been established.

Before you or your child are given it

Tell your doctor if:

1. you are pregnant or intend to become pregnant

It is not known whether the vaccine is harmful to an unborn baby when given to a pregnant woman. Your doctor will give you PNEUMOVAX 23 only if it is clearly needed.

2. you are breast-feeding

It is not known whether PNEUMOVAX 23 passes into breast milk. Your doctor will discuss the possible risks and benefits of you being given PNEUMOVAX 23 while breast-feeding.

3. you have any medical conditions, especially the following:

- heart or lung problems
- idiopathic thrombocytopenic purpura (ITP), a disease which

causes unusual bleeding or bruising under the skin

- blood problems
4. you have an infection or a high temperature

Your doctor may decide to delay your injection of PNEUMOVAX 23.

5. you are currently being treated or have recently been treated with radiotherapy or chemotherapy

Your doctor may decide to delay your injection of PNEUMOVAX 23.

6. you have been vaccinated with a pneumococcal vaccine before

Routine revaccination of people with normal immune systems previously vaccinated with PNEUMOVAX 23 is not recommended.

However, revaccination is recommended for people at highest risk of serious pneumococcal infection, at different times. Your doctor will decide if and when you need another injection of PNEUMOVAX 23.

7. you have any allergies to any other medicines or vaccines, or any other substances, such as foods, preservatives or dyes.

If you have not told your doctor about any of the above, tell them before you or your child are given an injection of PNEUMOVAX 23.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

PNEUMOVAX 23 may not work as well as it should if you or your child are taking or receiving medicines that decrease the immune system, such as corticosteroids (e.g. prednisone), cyclosporin, or chemotherapy.

PNEUMOVAX 23 should not be given at the same time as

ZOSTAVAX®. For more information about these vaccines, talk to your doctor or health care provider, because it may be better to get these vaccines at least 4 weeks apart.

Your doctor will advise you if you are taking or receiving any of these or other medicines that decrease the immune system. Your doctor will decide whether or not to give the vaccine.

How PNEUMOVAX 23 is given

How much is given

Your doctor will decide on the dose of PNEUMOVAX 23 that you or your child will be given.

The usual dose of PNEUMOVAX 23 is 0.5 mL. The dose of the vaccine is the same for everyone.

Usually only one injection is needed to help protect against pneumococcal disease. However, if you are at increased risk of serious pneumococcal infection, you may need to have a second injection. Your doctor will decide if and when you need a second injection of PNEUMOVAX 23.

How it is given

PNEUMOVAX 23 is given as an injection by a doctor or trained nurse, either into a muscle, such as your upper arm or mid-thigh, or under the skin. The vaccine should not be injected directly into veins (intravenously).

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well during or after having had an injection of PNEUMOVAX 23.

PNEUMOVAX 23 helps protect most people from pneumococcal infections, but it may have unwanted

side effects in a few people. All medicines and vaccines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you or your child has any of the following and if they are troublesome or ongoing:

- soreness, redness, warmth, swelling or hard lump where you had the injection. These may be more common and intense after a second shot than after the first shot.
- fever
- chills
- headache
- unusual tiredness or weakness
- generally feeling unwell
- nausea, vomiting

These are usually mild side effects of PNEUMOVAX 23. They usually improve or disappear within a few days.

Tell your doctor immediately if you or your child notice any of the following:

- aching muscles, muscle tenderness or weakness, not caused by exercise
- decreased ability to move limb
- painful or swollen joints
- tingling or numbness of the hands or feet
- swollen and painful lymph glands
- unusual bleeding or bruising
- convulsions or fits due to fever

These may be serious side effects. You may need urgent medical attention. These side effects are rare.

Allergic Reaction or Other Serious Conditions:

As with all vaccines given by injection, there is a very small risk of

a serious allergic reaction or other serious conditions.

Tell your doctor immediately or go to accident and emergency at your nearest hospital if you or your child notice any of the following:

- skin rash, itching
- pinkish, itchy swellings on the skin, also called hives or nettle rash
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- swelling of other parts of the body
- shortness of breath, wheezing or trouble breathing

These are serious side effects. If you have them, you may have had a serious allergic reaction or other serious reaction to PNEUMOVAX 23. You may need urgent medical attention or hospitalisation. Most of these side effects occur within the first few hours of vaccination but some may occur later.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Storage

PNEUMOVAX 23 is usually stored in the doctor's surgery or clinic, or at the pharmacy. However if you need to store PNEUMOVAX 23:

- **Keep it where children cannot reach it.**
- **Keep it in the refrigerator, but not in the door compartment.**
- **Do not put PNEUMOVAX 23 in the freezer, as freezing destroys the vaccine.**
- **Keep the injection in the original pack until it is time for it to be given.**

Product description

What it looks like

PNEUMOVAX 23 comes in glass vials or pre-filled syringes.

Ingredients

Active ingredient:

The active ingredient of PNEUMOVAX 23 is a mixture of inactive parts from 23 of the most common types of pneumococcal bacteria. Each 0.5 mL of vaccine contains 25 micrograms of each polysaccharide type.

Inactive ingredients:

- phenol
- sodium chloride
- water for injection

PNEUMOVAX 23 is made without any human blood or blood products.

The manufacture of this product includes exposure to bovine derived materials. No evidence exists that any case of vCJD (considered to be the human form of bovine spongiform encephalopathy) has resulted from the administration of any vaccine product.

Supplier

PNEUMOVAX 23 is supplied in Australia by:

Seqirus (Australia) Pty Ltd.,
63 Poplar Road
PARKVILLE VIC 3052

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Australian Register Numbers:
PNEUMOVAX 23 vials -
AUST R 10507

PNEUMOVAX 23 pre-filled
syringes - AUST R 222235

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